Available products for snakebite envenoming

North America

Anavip (Instituto Bioclon/Laboratorios Silanes, S. A. de C. V., Mexico)

Alternative name(s): Antivipmyn

Chemical name: N/A

CAS number: N/A

PCR ID: 1383

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Store at room temperature (up to 25 ºC (77 ºF)). Brief temperature excursions are permitted up to 40 ºC (104 o F) - Do not freeze

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

ANAVIP [crotalidae immune F(ab')2 (equine)] is a sterile, lyophilized, polyvalent preparation of equine immunoglobulin F(ab')2 fragments, manufactured from the plasma of horses immunized with venom of Bothrops asper and Crotalus simus (formerly Crotalus durissus). The product is obtained by pepsin digestion of horse plasma to remove the Fc portion of immunoglobulin, followed by fractionation and purification steps. The F(ab')2 content is not less than 85%, F(ab') content is not more than 7%, and the product contains less than 5% intact immunoglobulin. Each vial contains no more than 120 mg of protein and will neutralize not less than 780 times the LD50 of Bothrops asper (Terciopelo or fer-de-lance) venom, 790 times the LD50 of Crotalus simus (formerly Crotalus durissus) (Central American Rattlesnake) venom, 244 times the LD50 of Crotalus adamanteus (Eastern Diamondback Rattlesnake) venom, 147 times the LD50 of Crotalus atrox (Western Diamondback Rattlesnake) venom, 185 times the LD50 of Crotalus scutulatus (Mohave Rattlesnake) venom, 28 times the LD50 of Agkistrodon contortrix (Copperhead) venom and 61 times the LD50 of Agkistrodon piscivorus (Cottonmouth or Water Moccasin) venom in a mouse neutralization assay. (https://www.fda.gov/media/92139/download)Anavip has been studied in clinical trials. It was terminated after Phase III/late stage (NCT00868309 and NCT00636116) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4565558/pdf/pntd.0003896.pdf, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4565558/pdf/pntd.0003896.pdf, although appears still available and registered.(https://pubmed.ncbi.nlm.nih.gov/32763251/; https://pubmed.ncbi.nlm.nih.gov/27806644/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Bioclon; Laboratorios Silanes

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase III, (Status: Unknown, March 2008-): *Phase 3 Multicenter Comparative Study to Confirm Safety and Effectiveness of the F(ab)2 Antivenom Anavip.* (CT number: NCT00636116, CT source: http://clinicaltrials.gov/show/NCT00636116)

Phase II, (Status: Unknown, November 2008-): *A Comparison of Crotalinae Equine Immune F(ab)2 Antivenom (Anavip) and Crotalidae Polyvalent Immune Fab,* (CT number: NCT00868309, CT source: https://clinicaltrials.gov/show/NCT00868309)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops asper; Crotalus durissus
Snake species *(Sources: other)*	**Bothrops asper (Terciopelo); Crotalus durissus (Central American Rattlesnake)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	United States of America
Regions	North America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Agkistrodon contortrix; Agkistrodon piscivorus; Crotalus adamanteus; Crotalus atrox; Crotalus horridus; Crotalus molossus; Crotalus oreganus; Crotalus ruber; Crotalus scutulatus; Crotalus spp.; Crotalus viridis; Sistrurus miliarius

	Tested in	Effective against (any efficacy data)
Snake species *(Sources: Other)*	Crotalus adamanteus (Eastern Diamondback Rattlesnake); Crotalus atrox (Western Diamondback Rattlesnake); Crotalus scutulatus (Mohave Rattlesnake); Agkistrodon contortrix (Copperhead); Agkistrodon piscivorus (Cottonmouth)	Crotalus adamanteus (Eastern Diamondback Rattlesnake); Crotalus atrox (Western Diamondback Rattlesnake); Crotalus scutulatus (Mohave Rattlesnake); Agkistrodon contortrix (Copperhead); Agkistrodon piscivorus (Cottonmouth or Water Moccasin)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA,SRA

Country(ies) where the product is in use: Mexico; United States of America

Region of use: North America

WHO prequalification: No

Antivipmyn TRI Fabotherapic (Instituto Bioclon/Laboratorios Silanes, S. A. de C. V., Mexico)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1326

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Antivipmyn® Tri Fabotherapic polyvalent snake antivenom is indicated for the treatment of intoxication by the bite of vipers. The active ingredients of Antivipmyn® Tri Fabotherapic are the F(ab)2 and Fab fragments of immunoglobulin G (IgG), and it does not contain albumin. The following study: Bothrops bites in Colombia: a multicenter study on the efficacy and safety of Antivipmyn-tri®, a polyvalent antivenom produced in Mexico found Antivipmyn Tri® to be efficient and safe for the treatment of Bothrops bites in Colombia (http://www.scielo.org.co/scielo.php?script=sci_abstract&pid=S0121-07932007000300002&lng=en&nrm=iso&tlng=en)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Laboratorios Silanes; Instituto Bioclon

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops asper; Crotalus durissus; Lachesis muta
Snake species *(Sources: other)*	**Bothrops spp.**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Mexico
Regions	North America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Crotalus durissus terrificus (Cascavel); Crotalus durissus durissus (South American rattlesnake); Bothrops asper (Fer-de-lance); Bothrops atrox (Common lancehead); Bothrops neuwiedii (Cabeça-de-capanga); Bothrops alternatus (Cruzeria); Bothrops jararacussu (Jararacussu); Bothrops venezuelensis (Barriga morada); Bothrops pictus (Desert lancehead); Bothrops brazili (Brazil's lancehead); Lachesis muta (Amazonian bushmaster); Lachesis stenophrys (Central American bushmaster)	Crotalus durissus terrificus (Cascavel); Crotalus durissus durissus (South American rattlesnake); Bothrops asper (Fer-de-lance); Bothrops atrox (Common lancehead); Bothrops neuwiedii (Cabeça-de-capanga); Bothrops alternatus (Cruzeria); Bothrops jararacussu (Jararacussu); Bothrops venezuelensis (Barriga morada); Bothrops pictus (Desert lancehead); Bothrops brazili (Brazil's lancehead); Lachesis muta (Amazonian bushmaster); Lachesis stenophrys (Central American bushmaster)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Mexico

Region of use: North America

WHO prequalification: No

Coralmyn (Instituto Bioclon/Laboratorios Silanes, S. A. de C. V., Mexico)

Alternative name(s): Micrurus antivenom; coral snake antivenom; Polyvalent Anti-coral Fabotherapic

Chemical name: N/A

CAS number: N/A

PCR ID: 1347

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Micrurus nigrocinctus (Black banded coral snake)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: up to 37°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

An open-label Phase III clinical trial of Coralmyn (anti-coral serum injectable solution, Instituto Bioclon, S.A. de C.V.) in male and female human patients of any age who present for emergency care following bites by coral snakes of genus Micrurus was completed in 2018 (https://clinicaltrials.gov/ct2/show/NCT01337245). The goal of this study was to determine if Coralmyn antivenom was capable in neutralizing the North American coral snake venoms as an alternative to the Wyeth NACSA product which was phased out in 2010. This trial as well as other preclinical studies, showed that Coralmyn is able to effectively neutralise the venom of coral snakes found in the US, including Micrurus tener and Micrurus fulvius and their neurotoxic effects (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3293456/). Another study however showed that it was ineffective against Micrurus spixii, Micrurus pyrrhocryptus, and Micruroides euryxanthus (https://pubmed.ncbi.nlm.nih.gov/28674788/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Bioclon; Laboratorios Silanes

Preclinical results status: Available

Preclinical sources:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3293456/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6428337/https://pubmed.ncbi.nlm.nih.gov/28674788/

Evidence of clinical trials? Yes

Phase III, (Status: Completed, -): *Emergency Treatment of Coral Snake Envenomation With Antivenom* (CT number: NCT01337245, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Micrurus nigrocinctus
Snake species *(Sources: other)*	**Micrurus nigrocinctus (Black banded coral snake)**
Snake family	**Elapidae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	Mexico
Regions	North America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Micrurus nigrocinctus (Black banded coral snake); Micrurus tener (Coral, Corallilo, Texas coralsnake); Micrurus fulvius (Eastern coralsnake, Florida coralsnake, Harlequin coralsnake); Micrurus spixii (Acavai, Amazonian coralsnake, Cobra-coral, Coral, Coral venenosa, Coral-verdadeira, Naca-naca, Serpent-corail, Spix's coralsnake); Micrurus surinamensis (Aquatic coralsnake, Cobra coral, Cobra-coral aquatica, Coral, Coral de agua, Coral venenosa, Corallilo, Himeralli, Kraalslang, Naca-naca, Water mio); Micrurus pyrrhocryptus; Micruroides euryxanthus	Micrurus nigrocinctus (Black banded coral snake); Micrurus tener (Coral, Corallilo, Texas coralsnake); Micrurus fulvius (Eastern coralsnake, Florida coralsnake, Harlequin coralsnake)
Snake family		Elapidae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Mexico

Region of use: North America

WHO prequalification: No

Crotalidae Polyvalent Immune Fab (ovine) (BTG International Inc., United States of America)

Alternative name(s): CroFab; FabAV

Chemical name: N/A

CAS number: N/A

PCR ID: 1382

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Crotalus atrox (Western Diamondback rattlesnake); Crotalus adamanteus (Eastern diamondback rattlesnake); Crotalus scutulatus (Mojave rattlesnake); Agkistrodon piscivorus (Cottonmouth or Water Moccasin)

Route of administration: Intravenous

Ig format: Fab immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

CROFAB is a sheep-derived antivenin indicated for the management of adult and paediatric patients with North American Crotalid envenomation. The term crotalid is used to describe the Crotalinae subfamily (formerly known as Crotalidae) of venomous snakes which includes rattlesnakes, copperheads and cottonmouths/water moccasins (https://www.fda.gov/media/74683/download). Raised from the venoms of four North American snakes - Crotalus atrox (Western Diamondback rattlesnake); Crotalus adamanteus (Eastern diamondback rattlesnake); Crotalus scutulatus (Mojave rattlesnake); Agkistrodon piscivorus (Cottonmouth or Water Moccasin), (https://www.fda.gov/media/74683/download), its efficacy has been proven in preclinical mice lethality studies against these source snakes, as well as against Crotalus helleri (Southern Pacific rattlesnake) (https://pubmed.ncbi.nlm.nih.gov/12447339/), Crotalus durissus (tropical rattlesnake) and Bothrops atrox (fer-de-lance) (https://pubmed.ncbi.nlm.nih.gov/15940091/) - both of which are South American vipers, and Agkistrodon contortrix (copperhead Moccasin) (https://pubmed.ncbi.nlm.nih.gov/27163225/).Prevalence of adverse events following CroFab administration have also been investigated, with the prevalence rate being set at 2.7% from retrospective studies (https://pubmed.ncbi.nlm.nih.gov/29688079/), with similarly low values obtained from another randomised controlled trial (https://pubmed.ncbi.nlm.nih.gov/30512122/). Comparative clinical studies of CroFab and similar antivenom products including Anavip (https://pubmed.ncbi.nlm.nih.gov/32763251/) and Antivenin (Crotalidae) Polyvalent (ACP) (https://pubmed.ncbi.nlm.nih.gov/7485708/), have been published, showing that CroFab is just as effective as the F(ab') immunoglobulin-based Anavip from Mexico (https://pubmed.ncbi.nlm.nih.gov/32763251/), and is 3.1 - 9.6 times more potent than ACP

(https://pubmed.ncbi.nlm.nih.gov/7485708/). Advanced clinical trials have proven its efficacy in neutralising the haemorrhagic effects of systemic snake envenomation in by multiple snake species (https://pubmed.ncbi.nlm.nih.gov/27806644/). Multiple clinical trials have been conducted: NCT00303303, NCT00636116, NCT00868309,NCT01864200 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4565558/)CroFab (https://crofab.com/) was first approved by the US FDA in 2000, and it received its latest supplementary approval in August 2018 (https://www.fda.gov/media/74683/download).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: BTG International Inc.

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/7485708/

Evidence of clinical trials? Yes

Phase IV, (Status: Unknown, -): *Safety and Cost-Effectiveness of a Clinical Protocol Implemented to Standardize the Use of Crotalidae Polyvalent Immune Fab Antivenom at an Academic Medical Center.* (CT number: 700216132, CT source: https://adis.springer.com/trials/700216132?userId=87273450&bpIds=3003761072&checksum=fc94a00a5408df8a251d43f6f835c0d79ae213f7-1649035943547-baa93c5dd39860b2cc4d3d55a16c83941bee7be6b786ff49950412c143d347ef7ae51639f012c9d79f2463a28fda6f485c6d7c60d89605b5cec873374ff9c1be)

Phase III, (Status: Unknown, March 2008-): *Phase 3 Multicenter Comparative Study to Confirm Safety and Effectiveness of the F(ab)2 Antivenom Anavip.* (CT number: NCT00636116, CT source: http://clinicaltrials.gov/show/NCT00636116)

Phase II, (Status: Unknown, November 2008-): *A Comparison of Crotalinae Equine Immune F(ab)2 Antivenom (Anavip) and Crotalidae Polyvalent Immune Fab,* (CT number: NCT00868309, CT source: https://clinicaltrials.gov/show/NCT00868309)

Phase: N/A, (Status: Unknown, June 2009-): *Retrospective Evaluation of CroFab - Efficacy in Severe Envenomation* (CT number: NCT00927381, CT source: http://clinicaltrials.gov/show/NCT00927381)

Phase IV, (Status: Unknown, May 2013-): *Randomized, Double-Blind, Placebo-Controlled Study: CroFabÂ® vs Placebo for Copperhead Snake Envenomation* (CT number: NCT01864200, CT source: https://clinicaltrials.gov/show/NCT01864200)

Production/source

	Derived from
Snake species *(Source: WHO)*	Agkistrodon piscivorus; Crotalus adamanteus; Crotalus atrox; Crotalus scutulatus
Snake species *(Sources: other)*	**Crotalus atrox (Coon-tail rattler, Víbora de cascabel, Víbora serrana, Western diamondback rattlesnake); Crotalus adamanteus (Eastern diamondback rattlesnake, Florida diamondback); Crotalus scutulatus (Mohave rattlesnake, Mojave rattlesnake, Víbora de cascabel); Agkistrodon piscivorus (Cottonmouth or Water Moccasin)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	United States of America
Regions	North America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent sheep immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Agkistrodon contortrix; Agkistrodon taylori; Crotalus horridus; Crotalus molossus; Crotalus oreganus; Crotalus ruber; Crotalus viridis; Sistrurus catenatus; Sistrurus miliarius
Snake species *(Sources: Other)*	Crotalus atrox (Coon-tail rattler, Víbora de cascabel, Víbora serrana, Western diamondback rattlesnake); Crotalus adamanteus (Eastern diamondback rattlesnake, Florida diamondback); Crotalus scutulatus (Mohave rattlesnake, Mojavé rattlesnake, Víbora de cascabel); Agkistrodon piscivorus (Cottonmouth or Water Moccasin); Crotalus helleri (Southern Pacific rattlesnake); Crotalus durissus (tropical rattlesnake); Bothrops atrox (fer-de-lance); Agkistrodon contortrix (copperhead Moccasin)	Crotalus atrox (Coon-tail rattler, Víbora de cascabel, Víbora serrana, Western diamondback rattlesnake); Crotalus adamanteus (Eastern diamondback rattlesnake, Florida diamondback); Crotalus scutulatus (Mohave rattlesnake, Mojavé rattlesnake, Víbora de cascabel); Agkistrodon piscivorus (Cottonmouth or Water Moccasin); Crotalus helleri (Southern Pacific rattlesnake); Crotalus durissus (tropical rattlesnake); Bothrops atrox (fer-de-lance); Agkistrodon contortrix (copperhead Moccasin)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding),Cytotoxic (tissue damage)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA,SRA

Country(ies) where the product is in use: United States of America

Region of use: North America

WHO prequalification: No

Faboterapico Polivalente Antiviperino (Birmex - Instituto Nacional de Higiene, Mexico)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1397

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This antivenom is a preparation of specific immunoglobulins modified by enzymatic digestion, lyophilized and free of albumin, with a neutralizing capacity of not less than 790 LD50 of Crotalus sp venom and not less than 780 LD50 of Bothrops sp. (https://dof.gob.mx/nota_detalle.php?codigo=5270654&fecha=28/09/2012#gsc.tab=0). The preclinical efficacy of this antivenom against the toxic effects of medically important Bothrops sp was tested, and concluded that, with the exception of coagulant and defibrinogenating activities of B. asper (Costa Rica) venom, this antivenom neutralizes toxic effects of various Bothrops sp venoms. Future studies are necessary to assess the efficacy of this antivenom against other viperid venoms (https://pubmed.ncbi.nlm.nih.gov/29466649/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Laboratorio de Biológicos y Reactivos de México (BIRMEX)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops asper
Snake species *(Sources: other)*	**Agkistrodon bilineatus, Bothrops asper, Crotalus basiliscus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Mexico
Regions	North America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Agkistrodon bilineatus; Bothrops atrox; Bothrops diporus; Bothrops jararaca; Bothrops mattogrossensis; Crotalus atrox; Crotalus basiliscus; Crotalus simus
Snake species *(Sources: Other)*	Bothrops sp.	Bothrops sp.
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Mexico

Region of use: North America

WHO prequalification: No

North American Equine Coral Snake Antivenin (Wyeth, USA)

Alternative name(s): Wyeth Antivenin (Micrurus fulvius); North American Coral Snake Antivenin; NASCA

Chemical name: N/A

CAS number: N/A

PCR ID: 1348

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Micrurus fulvius (Eastern coralsnake, Florida coralsnake, Harlequin coralsnake)

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

North American Coral Snake Antivenin (Equine) is a horse-derived antivenin indicated for the treatment of envenomation caused by North American coral snakes (Micrurus sp.) - First developed in the 1960s, production in the USA was discontinued by Wyeth in 2006, but recommenced in 2019.The North American Coral Snake Antivenin is a polyclonal IgG of equine origin, and produced by Wyeth® located in the United States using venom from Micrurus fulvius (Eastern coral snake). It was first developed in the 1960s, but production in the USA was discontinued in 2006 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3293456/), with production resuming in late-2019 (https://www.medscape.com/answers/168828-39125/what-is-the-treatment-for-coral-snake-envenomation). It has been tested in preclinical studies against American coral snake species - Micrurus fulvius, Micrurus tener and the Mexican coral snake venom, Micrurus nigrocinctus, and found to be effective against Micrurus fulvius venom only (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3293456/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Wyeth Pharmaceuticals

Preclinical results status: Available

Preclinical sources: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3293456/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6708478/

Evidence of clinical trials? Yes

Phase III, (Status: Unknown, May 2012-November 2016): *Emergency Treatment of Coral Snake Envenomation With Antivenom* (CT number: NCT01337245, CT source: https://clinicaltrials.gov/show/NCT01337245)

Production/source

	Derived from
Snake species *(Source: WHO)*	Micrurus fulvius
Snake species *(Sources: other)*	**Micrurus fulvius (Eastern coralsnake, Florida coralsnake, Harlequin coralsnake)**
Snake family	**Elapidae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	United States of America
Regions	North America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Micrurus tener
Snake species *(Sources: Other)*	Micrurus fulvius (Eastern coralsnake, Florida coralsnake, Harlequin coralsnake); Micrurus tener (Coral, Corallilo, Texas coralsnake)	Micrurus fulvius (Eastern coralsnake, Florida coralsnake, Harlequin coralsnake)
Snake family		Elapidae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA,SRA

Country(ies) where the product is in use: United States of America

Region of use: North America

WHO prequalification: No

Central America

BothroFAV (MicroPharm Ltd, United Kingdom)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1401

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Bothrops lanceolatus (Fer-de-lance, Le serpent, Le trigonocephale, Martinique lancehead, Vipere jaune)containing F(ab')2 fragments which have the property of neutralising Bothrops lanceolatus venom. These equine F(ab')2 fragments ligate venom antigens present in the circulation to form inactive F(ab')2-antigen complexes, reducing the amount fo free venom in the circulation

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

BothroFAV is a monovalent antivenom develoepd by Micropharm, UK, and indicated for the treatment of local and systemic envenomation by Bothrops lanceolatus. It contains F(ab')2 immunoglobulin fragments which have the property of neutralising Bothrops lanceolatus venom. These equine F(ab')2 fragments ligate venom antigens present in the circulation to form inactive F(ab')2-antigen complexes, reducing the amount fo free venom in the circulation (https://micropharm.co.uk/products/current_products/). Its efficacy has been proven by multiple preclinical studies (https://pubmed.ncbi.nlm.nih.gov/10080358/) (https://pubmed.ncbi.nlm.nih.gov/32831345/) and a clinical trial (https://pubmed.ncbi.nlm.nih.gov/7771608/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: MicroPharm Ltd

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/32831345/https://pubmed.ncbi.nlm.nih.gov/10080358/

Evidence of clinical trials? Yes

Phase: N/A, (Status: Results submitted, -): *Prevention of thromboses in human patients with Bothrops lanceolatus envenoming in Martinique: failure of anticoagulants and efficacy of a monospecific antivenom. Research Group on Snake Bites in Martinique* (CT number: N/A, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops lanceolatus
Snake species *(Sources: other)*	**Bothrops lanceolatus (Fer-de-lance, Le serpent, Le trigonocephale, Martinique lancehead, Vipere jaune)**
Snake family	**Viperidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	Martinique
Regions	Caribbean

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bothrops lanceolatus (Fer-de-lance, Le serpent, Le trigonocephale, Martinique lancehead, Vipere jaune)	Bothrops lanceolatus (Fer-de-lance, Le serpent, Le trigonocephale, Martinique lancehead, Vipere jaune)
Snake family		Viperidae
Risk category		Category 1 (Highest Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: SVMPs,PLA2s,SVSPs

Syndromic profiles: Haemorrhagic (bleeding),Cytotoxic (tissue damage)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: France; Martinique

Region of use: Central America

WHO prequalification: No

CoRal-ICP Liquid (Instituto Clodomiro Picado, Costa Rica)

Alternative name(s): Suero antiofídico anticoral (SAC-ICP) líquido

Chemical name: N/A

CAS number: N/A

PCR ID: 1346

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

CoRal-ICP is an equine antivenom raised against the coral snake M. nigrocinctus, and effective against Micrurus clarki, M. nigrocinctus and M. mosquitensis (https://pubmed.ncbi.nlm.nih.gov/32776004/). Preclinical results have shown that this antivenom presents a strong immunorecognition and neutralizing potency against Micrurus venoms having a PLA2-predominant phenotype, but largely fails to recognize antigens in 3FTx-predominant venoms, and hence, to neutralize their lethal effect in mice (https://pubmed.ncbi.nlm.nih.gov/27641749/). This antivenom has also demonstrated significant cross-recognition of M. dumerilii venom proteins, and accordingly, ability to neutralize its lethal effect. (https://pubmed.ncbi.nlm.nih.gov/26883873/). It also neutralizes lethality and myotoxicity of M. fulvius venom (https://pubmed.ncbi.nlm.nih.gov/12782085/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: University of Costa Rica (including the Clodomiro Picado Institute)

Preclinical results status: Available

Preclinical sources:
https://www.sciencedirect.com/science/article/pii/S004101019600150Xhttps://www.sciencedirect.com/science/article/pii/004101019400178B

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Micrurus nigrocinctus
Snake species *(Sources: other)*	**M. nigrocinctus (Central American Coral Snake)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Costa Rica
Regions	Central America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Micrurus fulvius; Micrurus spp.; Micrurus tener
Snake species *(Sources: Other)*	Micrurus dumerilii (Dumeril's Coral Snake)	Micrurus dumerilii; Micrurus fulvius; Micrurus tener; Micrurus nigrocinctus, Micrurus mosquitensis, Micrurus clarki
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Costa Rica; Panama; Nicaragua; Honduras

Region of use: Central America

WHO prequalification: No

PoliVal-ICP (Instituto Clodomiro Picado, Costa Rica)

Alternative name(s): Suero antiofídico polivalente

Chemical name: N/A

CAS number: N/A

PCR ID: 1305

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Central American snakes

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Both

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

PoliVal-ICP is a polyvalent antivenom that neutralizes venoms of almost all medically important snakes of Central America however, the neutralization scope of PoliVal-ICP does not cover the venoms of neurotoxic rattlesnakes distributed in South America (https://www.sciencedirect.com/science/article/pii/S1874391921002141?via%3Dihub). With the recent addition of the venom of the South American snake Crotalus pifanorum, which is now routinely included in the preparation of this antivenom, the antivenom has expanded its coverage to South American rattlesnake venom. PoliVal-ICP has been evaluated in clinical trials including randomized blinded clinical trial (1999, https://pubmed.ncbi.nlm.nih.gov/10340829/; 2006, https://pubmed.ncbi.nlm.nih.gov/16698053/, https://pubmed.ncbi.nlm.nih.gov/28708892/) and 2012, https://pubmed.ncbi.nlm.nih.gov/22146491/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: University of Costa Rica (including the Clodomiro Picado Institute)

Preclinical results status: Available

Preclinical sources:
https://www.binasss.sa.cr/revistas/rccm/v9n2/art7.pdfhttps://www.sciencedirect.com/science/article/pii/S1874391921002141?via%3Dihub

Evidence of clinical trials? Yes

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops asper; Crotalus simus; Lachesis stenophrys
Snake species *(Sources: other)*	**C. d. pifanorum, C. simus, Bothrops asper and Lachesis stenophrys**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Costa Rica
Regions	Central America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source : WHO)*	Agkistrodon bilineatus; Agkistrodon contortrix; Agkistrodon piscivorus; Atropoides indomitus; Atropoides mexicanus; Atropoides nummifer; Atropoides occiduus; Atropoides olmec; Atropoides picadoi; Bothriechis bicolor; Bothriechis lateralis; Bothriechis marchi; Bothriechis rowleyi; Bothriechis schlegelii; Bothriechis supraciliaris; Bothriechis thalassinus; Bothrops alternatus; Bothrops atrox; Bothrops barnetti; Bothrops brazili; Bothrops caribbaeus; Bothrops diporus; Bothrops jararaca; Bothrops jararacussu; Bothrops lanceolatus; Bothrops moojeni; Bothrops neuwiedi; Bothrops pictus; Bothrops spp.; Cerrophidion barbouri; Cerrophidion godmani; Cerrophidion petlalcalensis; Cerrophidion picadoi; Cerrophidion tzotzilorum; Crotalus adamanteus; Crotalus atrox; Crotalus basiliscus; Crotalus horridus; Crotalus viridis; Lachesis acrochorda; Lachesis melanocephala; Lachesis muta; Metlapilcoatlus indomitus; Metlapilcoatlus mexicanus; Metlapilcoatlus nummifer; Metlapilcoatlus occiduus; Metlapilcoatlus olmec; Mixcoatlus barbouri; Porthidium lansbergii; Porthidium nasutum; Porthidium ophryomegas

	Tested in	Effective against (any efficacy data)
Snake species *(Sources: Other)*	A. howardgloydi, A. picadoi is included in the paraspecific scope of PoliVal-ICP due to the antigenic similarity between this venom and the venom of B. asper. C. sasai is included in the paraspecific scope of PoliVal-ICP due to the antigenic similarity between this venom and the venom of C. simus and L. stenophrys. The paraspecificity of PoliVal-ICP toward the venoms of P. nasutum and P. ophryomegas is conferred by the venoms of C. simus and B. asper, respectively. The capacity of PoliVal-ICP to neutralize the venom of L. melanocephala is conferred by the venom of L. stenophrys used as immunogen. All homologous venoms of PoliVal-ICP contribute to the paraspecificity of the antivenom toward the venoms of B. lateralis and B. supraciliaris (https://www.sciencedirect.com/science/article/pii/S0041010118300308?via%3Dihub)	WHO: Manufacturer label claim of paraspecificity against Agkistrodon bilineatus, Agkistrodon contortrix, Agkistrodon piscivorus, Atropoides indomitus, Atropoides mexicanus, Atropoides nummifer, Atropoides occiduus, Atropoides olmec, Atropoides picadoi, Bothriechis bicolor, Bothriechis lateralis, Bothriechis marchi, Bothriechis rowleyi, Bothriechis schlegelii, Bothriechis supraciliaris, Bothriechis thalassinus, Bothrops alternatus, Bothrops atrox, Bothrops barnetti, Bothrops brazili, Bothrops caribbaeus, Bothrops diporus, Bothrops jararaca, Bothrops jararacussu, Bothrops lanceolatus, Bothrops moojeni, Bothrops neuwiedi, Bothrops pictus, Bothrops spp., Cerrophidion barbouri, Cerrophidion godmani, Cerrophidion petlalcalensis, Cerrophidion picadoi, Cerrophidion tzotzilorum, Crotalus adamanteus, Crotalus atrox, Crotalus basiliscus, Crotalus horridus, Crotalus viridis, Lachesis acrochorda, Lachesis melanocephala, Lachesis muta, Metlapilcoatlus indomitus, Metlapilcoatlus mexicanus, Metlapilcoatlus nummifer, Metlapilcoatlus occiduus, Metlapilcoatlus olmec, Mixcoatlus barbouri, Porthidium lansbergii, Porthidium nasutum, Porthidium ophryomegas
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Ecuador; Costa Rica; Panama; Nicaragua; Honduras; Guatemala

Region of use: Central America

WHO prequalification: No

Suero Antiofidico Polivalente Centroamericano BIOL CLB (Instituto Biologico Argentino S.A.I.C, Argentina)

Alternative name(s): BIOL CENTRAL AMERICAN ANTI-OPHIDIC SERUM – Crotalus-Lachesis-Bothrops (CLB)

Chemical name: N/A

CAS number: N/A

PCR ID: 1324

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Bothrops asper, Crótalus simus and Lachesis muta

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 35°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Suero Antiofidico Polivalente Centroamericano BIOL is raised from antibodies obtained by fractionating the plasma of healthy horses immunized with the venom of Central American vipers. Neutralizes the poisons of Central American snakes belonging to the genera Crotalus (Cascauella; Cascabel), Lachesis (Verrugosa; Cascabel muda; Mapanare) and Bothrops (Terciopelo; Barba amarilla)
(https://www.biol.com.ar/uploads/filemanager/Sueroantiofidico_Centroamericano_Prospecto.pdf)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Biologico Argentino S.A.I.C (BIOL)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops asper; Crotalus simus; Lachesis muta
Snake species *(Sources: other)*	**Bothrops asper, Crótalus simus and Lachesis muta**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Central America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Crotalus, Lachesis and Bothrops genera	Crotalus, Lachesis and Bothrops genera
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Nicaragua; Panama; Honduras

Region of use: Central America

WHO prequalification: No

South America

Antiveneno Crotálico (Instituto Nacional de Produccion de Biologicos, Argentina)

Alternative name(s): Crotalus AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1405

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Neutralizes Crotalus durissus terrificus (rattlesnake)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Nacional de Producción de Biológicos (ANLIS)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Crotalus durissus
Snake species *(Sources: other)*	**Crotalus durissus terrificus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Argentina
Regions	South America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Crotalus durissus terrificus	Crotalus durissus terrificus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Argentina

Region of use: South America

WHO prequalification: No

Antiveneno Micrurus (Instituto Nacional de Produccion de Biologicos, Argentina)

Alternative name(s): Micrurus AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1345

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Micrurus pyrrhocryptus (Argentinian coral snake)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Antiveno Micrurus is an antivenom product developed by the Instituto Nacional de Produccion de Biologicos, Argentina. It is a monovalent antivenom derived from the plasma of horses immunized with the venom of the Argentinian coral snake (https://www.argentina.gob.ar/salud/anlis/inpb/productos/antivenenos#enestapagina). It has recently been investigated in a preclinical study comparing its efficacy with that of an experimental polyvalent antivenom candidate developed against coral snakes found in Argentina (https://pubmed.ncbi.nlm.nih.gov/34303716/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Nacional de Producción de Biológicos (ANLIS)

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/34303716/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Micrurus corallinus; Micrurus spp.
Snake species *(Sources: other)*	**Micrurus pyrrhocryptus (Argentinian coral snake)**
Snake family	**Elapidae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	Argentina
Regions	South America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Micrurus pyrrhocryptus (Argentinian coral snake)	Micrurus pyrrhocryptus (Argentinian coral snake)
Snake family		Elapidae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Argentina

Region of use: South America

WHO prequalification: No

Soro Antibotrópico Pentavalente (Instituto Butantan, FUNED, Instituto Vital Brazil, CPPI, Brazil)

Alternative name(s): Bothrops AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1313

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Bothrops jararaca; Bothrops jararacussu; Bothrops moojeni; Bothrops alternatus; Bothrops neuwiedi

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Soro Antibotrópico Pentavalente is a polyspecific bothrops antivenom manufactured by Instituto Butantan, Fundação Ezequiel Dias (FUNED), Centro de Produção e Pesquisa de Imunobiológicos (CPPI) and Instituto Vital Brazil (IVB) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6863067/pdf/rpsp-43-e92.pdf). In 1993 a clinical trial was conducted to evaluate the safety and efficacy of the anti-bothropic serum (https://pubmed.ncbi.nlm.nih.gov/8327649/). Its ability to neutralize the venom of bites by snakes of the genera Bothrops, Bothriopsis and Porthidium is also confirmed by animal models laboratory. (http://www.funed.mg.gov.br/wp-content/uploads/2020/04/Bula-de-soro-antibotr%C3%B3pico-pentavalente-para-o-profissional-de-sa%C3%BAde-2020.pdf). A randomised blinded Phase II trial has been conducted to determine dosing in 1995 (https://www.sciencedirect.com/science/article/pii/0035920395906789) follow up by two randomised double blind comparative trials of South American polyvalent products (https://pubmed.ncbi.nlm.nih.gov/14702836/; https://www.bmj.com/content/329/7475/1129)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Butantan Institute, Fundacao Butantan; Ezequiel Dias Foundation, Fundação Ezequiel Dias (FUNED); Instituto Vital Brazil; Center for Production and Research of Immunobiology (CPPI)

Preclinical results status: Available

Preclinical sources: http://www.funed.mg.gov.br/wp-content/uploads/2020/04/Bula-de-soro-antibotr%C3%B3pico-pentavalente-para-o-profissional-de-sa%C3%BAde-2020.pdf

Evidence of clinical trials? Yes

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops alternatus; Bothrops jararaca; Bothrops jararacussu; Bothrops moojeni; Bothrops neuwiedi; Crotalus durissus; Lachesis muta
Snake species *(Sources: other)*	**Bothrops jararaca; Bothrops jararacuçu; Bothrops alternatus; Bothrops moojeni; Bothrops neuwiedi**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Brazil
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Bothrops atrox; Bothrops barnetti; Bothrops bilineatus; Bothrops brazili; Bothrops diporus; Bothrops leucurus; Bothrops marajoensis; Bothrops mattogrossensis; Bothrops pictus; Bothrops pubescens; Bothrops spp.; Bothrops taeniatus
Snake species *(Sources: Other)*	Bothrops jararaca; Bothrops jararacuçu; Bothrops cotiara; Bothrops urutú; Bothrops caiçaca; Bothriopsis spp and Porthidium spp	Bothrops jararaca; Bothrops jararacuçu; Bothrops cotiara; Bothrops urutú; Bothrops caiçaca; Bothriopsis spp and Porthidium spp
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Brazil

Region of use: South America

WHO prequalification: No

Soro Antibotrópico pentavalente e Crotálico (Instituto Butantan, FUNED, Instituto Vital Brazil, Brazil)

Alternative name(s): Bothrops-Crotalus AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1314

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Bothrops jararaca; Bothrops jararacussu; Bothrops alternatus; Bothrops moojeni; Bothrops neuwiedi; Crotalus durissus snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This polyspecific anti-bothrops and anti-crotalus antivenom is manufactured by Instituto Butantan, Fundação Ezequiel Dias (FUNED), Centro de Produção e Pesquisa de Imunobiológicos (CPPI) and Instituto Vital Brazil (IVB) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6863067/pdf/rpsp-43-e92.pdf). However FUNED maintains exclusive production rights (http://www.funed.mg.gov.br/soro-antibotropico-pentavalente-e-anticrotalico/). It is indicated in the treatment of Bothrops and Crotalus snakes (http://www.funed.mg.gov.br/soro-antibotropico-pentavalente-e-anticrotalico/). It is currently being used as the standard therapy within of a Phase IIb clinical trial testing the safety and efficacy of a new freeze-dried trivalent anti-venom for Brazilian snakebites (https://www.isrctn.com/ISRCTN12845255), the results of which were recently published (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5720814/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Vital Brazil; Ezequiel Dias Foundation, Fundação Ezequiel Dias (FUNED); Butantan Institute, Fundacao Butantan

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops alternatus; Bothrops jararaca; Bothrops jararacussu; Bothrops moojeni; Bothrops neuwiedi; Crotalus durissus
Snake species *(Sources: other)*	**Bothrops jararaca; Bothrops jararacuçu; Bothrops alternatus; Bothrops moojeni; Bothrops neuwiedi; Crotalus durissus terrificus; Crotalus durissus collilineatus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Brazil
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Bothrops atrox; Bothrops bilineatus; Bothrops brazili; Bothrops diporus; Bothrops leucurus; Bothrops marajoensis; Bothrops mattogrossensis; Bothrops oligobalius; Bothrops pubescens; Bothrops spp.; Bothrops taeniatus
Snake species *(Sources: Other)*	Bothrops jararaca; Bothrops jararacuçu; Bothrops cotiara; Bothrops urutú; Bothrops caiçaca; Crotalus terrificus; Crotalus collilineatus	Bothrops jararaca; Bothrops jararacuçu; Bothrops cotiara; Bothrops urutú; Bothrops caiçaca; Crotalus terrificus; Crotalus collilineatus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Brazil

Region of use: South America

WHO prequalification: No

Soro Antibotrópico pentavalente e Laquético (Instituto Butantan, FUNED, Instituto Vital Brazil, Brazil)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1325

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Bothrops jararaca; Bothrops jararacuçu; Bothrops alternatus; Bothrops moojeni; Bothrops neuwiedi;Lachesis muta (surucucu)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Antibothropic (pentavalent) and antilaquetic serum is indicated for the treatment of poisoning caused by the bite of snakes of the Bothrops - Bothrops jararaca; Bothrops jararacuçu; Bothrops alternatus; Bothrops moojeni; Bothrops neuwiedi and Lachesis - Lachesis muta (surucucu) genera (https://consultaremedios.com.br/soro-antibotropico-pentavalente-e-antilaquetico/bula). It is independently manufactured by three Brazilian public research institutes is produced by Instituto Butantan, Fundação Ezequiel Dias (FUNED), and Instituto Vital Brazil (IVB) but widely referred to as the Instituto Butantan antivenom by most Brazilian pharmaceutical websites (https://consultaremedios.com.br/soro-antibotropico-pentavalente-e-antilaquetico/bula) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4565558/).paraparaIts ability to neutralize the venom of bites by snakes of the Bothrops and Lachesis genus is confirmed by animal models laboratory experimental results listed in the product insert (https://buladeremedio.net/instituto_butantan/0/soro_antibotropico_laquetico). It has been investigated in a comparative efficacy clinical trial with the specific Bothrops atrox-Lachesis antivenom, and it was shown that both antivenom products had similar safety and efficacy profiles (https://pubmed.ncbi.nlm.nih.gov/14702836/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Butantan Institute, Fundacao Butantan; Instituto Vital Brazil; Ezequiel Dias Foundation, Fundação Ezequiel Dias (FUNED)

Preclinical results status: Available

Preclinical sources: http://www.funed.mg.gov.br/wp-content/uploads/2020/04/Bula-para-o-profissional-do-soro-antibotr%C3%B3pico-e-antilaqu%C3%A9tico_v16042020.pdf

Evidence of clinical trials? Yes

Phase II, (Status: Results submitted, -): *Clinical trial of two antivenoms for the treatment of Bothrops and Lachesis bites in the north eastern Amazon region of Brazil* (CT number: N/A, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops alternatus; Bothrops jararaca; Bothrops jararacussu; Bothrops moojeni; Bothrops neuwiedi; Lachesis muta
Snake species *(Sources: other)*	**Bothrops jararaca; Bothrops jararacuçu; Bothrops alternatus; Bothrops moojeni; Bothrops neuwiedi; ; Lachesis muta**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Brazil
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Bothrops atrox; Bothrops bilineatus; Bothrops brazili; Bothrops diporus; Bothrops leucurus; Bothrops marajoensis; Bothrops mattogrossensis; Bothrops pubescens; Bothrops spp.; Bothrops taeniatus
Snake species *(Sources: Other)*	Bothrops jararaca; Bothrops jararacuçu; Bothrops cotiara; Bothrops urutú; Bothrops caiçaca; Lachesis muta	Bothrops jararaca; Bothrops jararacuçu; Bothrops cotiara; Bothrops urutú; Bothrops caiçaca; Lachesis muta
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Brazil

Region of use: South America

WHO prequalification: No

Soro Anticrotálico (Instituto Butantan, FUNED, Instituto Vital Brazil, CPPI, Brazil)

Alternative name(s): Crotalus AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1407

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Crotalus durissus (Amaru, Asakamio, Cascabel, Cascavel, Ma ára, Maracá, Maracabóia, Palla, Sak-kah-sak, Saka sneki, South American rattlesnake)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The heterologous and hyperimmune anticrotalic serum is presented in ampoules containing 10 mL of injectable solution of the F(ab')2 fraction of purified specific immunoglobulins obtained from plasma of horses hyperimmunized with a mixture of crotamino-positive venoms from snakes of the genus Crotalus (http://www.funed.mg.gov.br/wp-content/uploads/2020/04/Bula-do-soro-anticrot%C3%A1lico-para-o-profissional-2020.pdf). It is manufactured by three Brazilian public institutes including - Instituto Butantan, Fundação Ezequiel Dias (FUNED), Centro de Produção e Pesquisa de Imunobiológicos (CPPI) and Instituto Vital Brazil (IVB). There are no controlled clinical trials to evaluate the efficacy of Funed's anticrotalic serum, which is of equine origin. (heterologous), but its ability to neutralize the venom of snake bites of the genus Crotalus is proven by laboratory animal models (http://www.funed.mg.gov.br/wp-content/uploads/2020/04/Bula-do-soro-anticrot%C3%A1lico-para-o-profissional-2020.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Butantan Institute, Fundacao Butantan; Instituto Vital Brazil; Ezequiel Dias Foundation, Fundação Ezequiel Dias (FUNED); Center for Production and Research of Immunobiology (CPPI)

Preclinical results status: Available

Preclinical sources: http://www.funed.mg.gov.br/wp-content/uploads/2020/04/Bula-do-soro-anticrot%C3%A1lico-para-o-profissional-2020.pdf

Evidence of clinical trials? No

Production/source

	Derived from
Snake species *(Source: WHO)*	Crotalus durissus
Snake species *(Sources: other)*	**Crotalus durissus (Amaru, Asakamio, Cascabel, Cascavel, Ma ára, Maracá, Maracabóia, Palla, Sak-kah-sak, Saka sneki, South American rattlesnake)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Brazil
Regions	South America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Crotalus durissus (Amaru, Asakamio, Cascabel, Cascavel, Ma ára, Maracá, Maracabóia, Palla, Sak-kah-sak, Saka sneki, South American rattlesnake)	Crotalus durissus (Amaru, Asakamio, Cascabel, Cascavel, Ma ára, Maracá, Maracabóia, Palla, Sak-kah-sak, Saka sneki, South American rattlesnake); and other subspecies of Crotalus durissus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Brazil

Region of use: South America

WHO prequalification: No

Soro Antielapídico Bivalente (Fundacao Ezequiel Dias & Butantan Institute, Brazil)

Alternative name(s): Micrurus AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1343

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Micrurus frontalis; Micrurus corallinus

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The bivalent Micrurus (coral snake) antivenom is manufactured by both the Instituto Butantan and the Fundação Ezequiel Dias (FUNED). It is a bivalent antivenom that exists as an injectable solution of the F(ab')2 fraction of purified specific immunoglobulins, proteins found in plasma of horses hyperimmunized against both snake species (http://www.funed.mg.gov.br/wp-content/uploads/2020/04/Bula-soro-antielap%C3%ADdico-bivalente-para-o-paciente-2020.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Butantan Institute, Fundacao Butantan; Ezequiel Dias Foundation, Fundação Ezequiel Dias (FUNED)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Micrurus corallinus
Snake species *(Sources: other)*	**Micrurus frontalis; Micrurus corallinus**
Snake family	**Elapidae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	Brazil
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Micrurus spp.
Snake species *(Sources: Other)*	Micrurus frontalis; Micrurus corallinus	Micrurus frontalis; Micrurus corallinus
Snake family		Elapidae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Brazil

Region of use: South America

WHO prequalification: No

Suero Antibotrópico Polivalente (Instituto Nacional de Salud, Peru)

Alternative name(s): Suero Antibotrópico Polivalente Heterólogo (Equino)

Chemical name: N/A

CAS number: N/A

PCR ID: 1300

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Suero Antibotrópico Polivalente is a polyvalent antibotropic serum solution of specific immunoglobulins obtained from the plasma of horses hyperimmunized with snake venoms of the Bothrops genus. Studies have shown that this antivenom neutralized the main toxicological activities e.g. lethality and hemorrhage induced by the venoms and thus is effective to treat snake bite victims inflicted by Bothrops snakes, particularly B. atrox. (https://pubmed.ncbi.nlm.nih.gov/27641748/). Further product details can be found at http://bvs.minsa.gob.pe/local/MINSA/2929.pdf and http://www.digemid.minsa.gob.pe/UpLoad%5CUpLoaded%5CPDF/12-07_Suero_antiofidico.pdf

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Peruvian Ministry of Health (MINSA) (including INS and National Center for Public Health)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrocophias hyoprora; Bothrocophias microphthalmus; Bothrops atrox; Bothrops brazili; Bothrops pictus
Snake species *(Sources: other)*	**Bothrops atrox (common lancehead)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Peru
Regions	South America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bothrops atrox (common lancehead); Bothrops brazili (Brazil's lancehead); Bothrops pictus (desert lancehead), Bothrops barnetti (Barnett's lancehead), Bothrocophias hyoprora (Amazonian toad-headed pitviper)	Bothrops atrox (common lancehead); Bothrops brazili (Brazil's lancehead); Bothrops pictus (desert lancehead), Bothrops barnetti (Barnett's lancehead), Bothrocophias hyoprora (Amazonian toad-headed pitviper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Peru

Region of use: South America

WHO prequalification: No

Suero Anticoral Polivalente (Instituto Nacional de Salud, Colombia)

Alternative name(s): Antiveneno Anticoral Polivalente Suero Antimicrúrico; Antiveneno Anticoral Polivalente (AAP)

Chemical name: N/A

CAS number: N/A

PCR ID: 1349

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Micrurus dumerilii, Micrurus mipartitus, Micrurus izosonus and Micrurus surinamensis

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Suero Anticoral Polivalente is a polyvalent antivenom against coral snake envenomings. It is composed of specific immunoglobulins for the treatment of envenoming caused by venomous snakes of the Micrurus genus, produced by the Instituto Nacional de Salud (INS), Colombia. Each 10 ml of the serum neutralizes at least: 2 mg of venom from Micrurus dumerilii, Micrurus mipartitus, Micrurus izosonus and Micrurus surinamensis.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Colombian National Institute of Health, Instituto Nacional de Salud (INS)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Micrurus mipartitus; Micrurus spp.; Micrurus surinamensis
Snake species *(Sources: other)*	**Micrurus dumerilii, Micrurus mipartitus, Micrurus izosonus y Micrurus surinamensis**
Snake family	**Elapidae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	Colombia
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent immunization, details unclear

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Micrurus lemniscatus
Snake species *(Sources: Other)*	Andean, Atlantic and Pacific Regions, species:Micrurus dumerilii: Coral, Coralilla, Coral capuchina and Micrurus mipartitus: Coral rabo de ají, cabeza de chocho, candelilla, coral rabo de candela, gargantilla.Orinoquia and Amazonía region, species: Micrurus isozonus: Coral de franjas iguales, Coral, Acaví (tribu guahibo), Huayamacaicha (tribu Cuiva) and Micrurus surinamensis: Coral de agua.	Andean, Atlantic and Pacific Regions, species:Micrurus dumerilii: Coral, Coralilla, Coral capuchina and Micrurus mipartitus: Coral rabo de ají, cabeza de chocho, candelilla, coral rabo de candela, gargantilla.Orinoquia and Amazonía region, species: Micrurus isozonus: Coral de franjas iguales, Coral, Acaví (tribu guahibo), Huayamacaicha (tribu Cuiva) and Micrurus surinamensis: Coral de agua.
Snake family		Elapidae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Colombia

Region of use: South America

WHO prequalification: No

Suero Anticrotálico Monovalente (Instituto Nacional de Salud, Peru)

Alternative name(s): Suero Anticrotálico Monovalente Heterólogo (Equino)

Chemical name: N/A

CAS number: N/A

PCR ID: 1406

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Crotalus durissus terrificus (Cascabel)

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The monovalent anticrotalic serum is a solution of specific immunoglobulins obtained from the serum of horses hyperimmunized with snake venoms of the Crotalus genus (http://bvs.minsa.gob.pe/local/MINSA/2929.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Peruvian Ministry of Health (MINSA) (including INS and National Center for Public Health)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Crotalus durissus
Snake species *(Sources: other)*	**Crotalus durissus terrificus (Cascabel)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Peru
Regions	South America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Crotalus durissus terrificus (Cascabel)	Crotalus durissus terrificus (Cascabel)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Peru

Region of use: South America

WHO prequalification: No

Suero Antilachésico Monovalente (Instituto Nacional de Salud, Peru)

Alternative name(s): Suero Antilachésico Monovalente Heterólogo (Equino)

Chemical name: N/A

CAS number: N/A

PCR ID: 1323

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom Lachesis muta (Amazonian bushmaster)

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The polyvalent anti lachésico serum is a solution of specific immunoglobulins obtained from the plasma of horses hyperimmunized with Lachesis muta muta venom. Further product information can be found at (http://bvs.minsa.gob.pe/local/MINSA/2929.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Peruvian Ministry of Health (MINSA) (including INS and National Center for Public Health)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Lachesis muta
Snake species *(Sources: other)*	**Lachesis muta muta (Amazonian bushmaster)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Peru
Regions	South America

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Lachesis muta muta (Amazonian bushmaster)	Lachesis muta muta (Amazonian bushmaster)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Peru

Region of use: South America

WHO prequalification: No

Suero Antiofídico (BIOTECFAR, Venezuela)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1376

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Bothrops (B. colombiensis, B. venezuelensis and B. atrox) and Crotalus (C. durisus cumanensis, C. pifanorum and C. vegrandis)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The treatment for snakebite in Venezuela is a multipurpose antivenom serum prepared by the Centro de Biotecnología de la Facultad de Farmacia de la Universidad Central de Venezuela. For its production, venom extracted from snakes of the genera Bothrops (B. colombiensis, B. venezuelensis and B. atrox) and Crotalus (C. durisus cumanensis, C. pifanorum and C. vegrandis) is used, which, when inoculated into horses, produce the specific antibodies capable of neutralizing venoms.https://sostelemedicina.ucv.ve/serpiente/ArchivosHTML/elveneno.htm

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: BIOTECFAR

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops atrox; Bothrops cf. atrox; Bothrops venezuelensis; Crotalus durissus; Porthidium lansbergii
Snake species *(Sources: other)*	**Bothrops (B. colombiensis, B. venezuelensis and B. atrox) and Crotalus (C. durissus cumanensis, C. pifanorum and C. vegrandis)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Venezuela
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bothrops (B. colombiensis, B. venezuelensis and B. atrox) and Crotalus (C. durissus cumanensis, C. pifanorum and C. vegrandis)	Bothrops (B. colombiensis, B. venezuelensis and B. atrox) and Crotalus (C. durissus cumanensis, C. pifanorum and C. vegrandis)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Venezuela

Region of use: South America

WHO prequalification: No

Suero Antiofídico Anticoral Polivalente Liofilizado (Laboratorios Biologicos PROBIOL Ltda, Colombia)

Alternative name(s): Anti-Micruricos-Corales

Chemical name: N/A

CAS number: N/A

PCR ID: 1350

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 30ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Suero Antiofídico Anticoral Polivalente Liofilizado is a lyophilised, polyvalent product against coral snakes produced by private manufacturer, PROBIOL. Further information on the technical specifications of the product can be found at: https://www.farmtrading.com.ec/wp-content/uploads/2020/01/Ficha-T%C3%A9cnica-Suero-Anticoral-PROBIOL.pdf

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Laboratorios Probiol

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Micrurus spixii; Micrurus surinamensis
Snake species *(Sources: other)*	**Micrurus spp.**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Colombia
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Micrurus mipartitus; Micrurus spp.
Snake species *(Sources: Other)*	
Snake family	
Risk category	

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Colombia

Region of use: South America

WHO prequalification: No

Suero Antiofidico Polivalente (Instituto Nacional de Salud, Colombia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1318

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Bothrops and Crotalus

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The National Institute of Health (INS) in Colombia produces Suero Antiofidico Polivalente, a polyvalent antivenom product which has the greatest neutralizing capacity in Colombia (due to immunization strategy) but is can be used in wider South America. The INS polyvalent antivenom is manufactured with the venom of various types of snakes, from juvenile and adult specimens, which makes it very effective for the bite of Bothrops sp., Crotalus sp. and Lachesis sp. Further product information can be found at https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/IA/INS/suero1-2.pdfThe INS polyvalent antivenom serum is commercially available as a box with two vials of 10 mL, containing injectable solution specific immunoglobulin G (IgG) purified from hyperimmune plasma of equine specimens immunized with snake venom of the Bothrops, Crotalus and Lachesis genera (https://www.ins.gov.co/lineas-de-accion/Produccion/SiteAssets/Paginas/suero-antiofidico-polivalente/Inserto%20Suero%20Antiof%C3%ADdico%20Polivalente.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Colombian National Institute of Health, Instituto Nacional de Salud (INS)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops asper; Bothrops atrox; Crotalus durissus; Lachesis muta
Snake species *(Sources: other)*	**Bothrops asper (fer-de-lance), B. atrox, Crotalus durissus (South American rattlesnake), Lachesis muta (Amazonian bushmaster), L. acrochorda (Chocoan bushmaster) and P. lansbergii (Lansberg's hognosed pitviper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Colombia
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent immunization, details unclear

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Bothriechis aurifer; Bothriechis nigroviridis; Bothriechis supraciliaris; Bothrocophias campbelli; Bothrocophias colombianus; Bothrocophias myersi; Bothrops bilineatus; Bothrops diporus; Bothrops jararaca; Bothrops mattogrossensis; Bothrops pictus; Bothrops spp.; Porthidium arcosae; Porthidium dunni; Porthidium hespere; Porthidium porrasi; Porthidium volcanicum; Porthidium yucatanicum
Snake species *(Sources: Other)*	Bothrops spp: Taya equis, cuatro narices, cabeza de candado, mapaná, boquidorá, mapanare, granadilla, veinticuatro, barba amarilla, patoco, patoquilla, rabo de chucha, montuna, jergón, podridora, víbora depestaña, lora, terciopelo, lorito, orito, pelo de gato, terciopelo, rabiseca, víbora de pestaña ó víbora de tierra fría.Crotalus sp. CascabelLachesis sp. Verrugoso, Rieca	Bothrops spp: Taya equis, cuatro narices, cabeza de candado, mapaná, boquidorá, mapanare, granadilla, veinticuatro, barba amarilla, patoco, patoquilla, rabo de chucha, montuna, jergón, podridora, víbora depestaña, lora, terciopelo, lorito, orito, pelo de gato, terciopelo, rabiseca, víbora de pestaña ó víbora de tierra fría.Crotalus sp. CascabelLachesis sp. Verrugoso, Rieca

Tested in	Effective against (any efficacy data)
Snake family	Viperidae
Risk category	Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Colombia

Region of use: South America

WHO prequalification: No

Suero Antiofidico Polivalente BIOL (Instituto Biologico Argentino S.A.I.C, Argentina)

Alternative name(s): BIOL MULTIPURPOSE ANTI-OPHIDIC SERUM

Chemical name: N/A

CAS number: N/A

PCR ID: 1394

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Crotalus durissus, Bothrops alternatus and Bothrops neuwiedii

Route of administration: Intravenous; Intramuscular

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Suero Antiofidico Polivalente BIOL is a polyvalent antivenom developed by the Instituto Biologico Argentino S.A.I.C and indicated for the neutralisation of local and systemic envenomation caused by found snake species commonly found in Argentina, including - Crotalus durissus, Bothrops alternatus and Bothrops neuwiedii (https://www.biol.com.ar/uploads/filemanager/Suero%20Antiofifico%20Polivalente%20Biol.pdf; https://ofidismo.biol.com.ar/suero.php).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Biologico Argentino S.A.I.C (BIOL)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Atropoides nummifer; Bothrops asper; Crotalus simus; Metlapilcoatlus nummifer
Snake species *(Sources: other)*	**Crotalus durissus, Bothrops alternatus and Bothrops neuwiedii**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Argentina
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Crotalus durissus, Bothrops alternatus; Bothrops neuwiedii; Crotalus durissus terrificus, Bothrops ammodytoides and Bothrops diporus	Crotalus durissus, Bothrops alternatus; Bothrops neuwiedii; Crotalus durissus terrificus, Bothrops ammodytoides and Bothrops diporus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Guatemala

Region of use: South America

WHO prequalification: No

Suero Antiofidico Polivalente Botropico/Crotalico (Ministerio de Salud y Deportes, Instituto Nacional de Laboratorios De Salud, Bolivia)

Alternative name(s): Bothrops-Crotalus AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1400

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

BOTROPIC/CROTALIC POLYVALENT ANTI-OPHID SERUM Anti-venom for Yoperojobobo and Rattlesnake bites.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Bolivian National Institute of Health Laboratories (INLASA)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops atrox; Bothrops neuwiedi; Crotalus durissus
Snake species *(Sources: other)*	**B. neuwiedi bolivianus and C.d. terrificus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Bolivia
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent immunization, details unclear

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Bothrops jonathani
Snake species *(Sources: Other)*	
Snake family	
Risk category	

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Bolivia

Region of use: South America

WHO prequalification: No

Suero Antiofidico Polivalente Botropico/Laquesico (Ministerio de Salud y Deportes, Instituto Nacional de Laboratorios De Salud, Bolivia)

Alternative name(s): Bothrops-Lachesis AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1327

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Suero Antiofidico Polivalente Botropico/Laquesico is a polyvalent anti-ophid serum against Yoperojobobo (Bothrops atrox) and Pucarara (Lachesis muta) bites. The Instituto Nacional de Laboratorios de Salud (INLASA), isresponsible for antivenom production in Bolivia. Production at INLASA started in 2000 and since produces anti-viperid and anti-lachesis products that are generated in donkeys. These antivenoms are used exclsuively in Bolivia (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6863067/pdf/rpsp-43-e92.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Bolivian National Institute of Health Laboratories (INLASA)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops atrox; Bothrops neuwiedi; Lachesis muta
Snake species *(Sources: other)*	**Bothrops neuwiedi bolivianus; Lachesis muta**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Bolivia
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent immunization, details unclear

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bothrops neuwiedi bolivianus; Lachesis muta	Bothrops neuwiedi bolivianus; Lachesis muta
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Bolivia

Region of use: South America

WHO prequalification: No

Suero Antiofidico Polivalente Liofilizado (Laboratorios Biologicos PROBIOL Ltda, Colombia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1321

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 30ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Suero Antiofidico Polivalente is a lyophilized polyvalent antivenom manufactured by Probiol. The product contains immunoglobulins of equine origin with a high content of neutralizing antibodies against the venom of snakes of the Bothrops, Lachesis and Crotalus genera. Further product information can be found at https://www.farmtrading.com.ec/wp-content/uploads/2020/01/Ficha-T%C3%A9cnica-Suero-Polivalente-PROBIOL.pdfThis product was used in a retrospective observational study in Suriname to assess patient outcomes including mortality and legnth of hospital stay. It found adverse reactions during ASV administration were mostly mild, however there is an urgent need for randomized controlled prospective studies in low- and middle-income countries with proper registration of parameters to evaluate the efficacy of antivenom products like this one (https://pubmed.ncbi.nlm.nih.gov/32662397/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Laboratorios Probiol

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops asper; Bothrops atrox; Crotalus durissus; Lachesis muta
Snake species *(Sources: other)*	**Bothrops atrox, Bothrops asper, Lachesis muta, Crotalus durissus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Colombia
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Lachesis acrochorda
Snake species *(Sources: Other)*	
Snake family	
Risk category	

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Colombia

Region of use: South America

WHO prequalification: No

Suero Bothropico Bivalente (Instituto Nacional de Produccion de Biologicos, Argentina)

Alternative name(s): Bivalent Bothrops AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1392

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Neutralizes venom from Bothrops alternatus and Bothrops newiedii (vipers Yarará grande or de la cruz and Yarará chica respectively)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Nacional de Producción de Biológicos (ANLIS)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops alternatus; Bothrops ammodytoides
Snake species *(Sources: other)*	**B. alternatus and B. diporus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Argentina
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: Other)*	
Snake family	
Risk category	

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Argentina

Region of use: South America

WHO prequalification: No

Suero Bothropico Tetravalente (Instituto Nacional de Produccion de Biologicos, Argentina)

Alternative name(s): Tetravalent Bothrops AV

Chemical name: N/A

CAS number: N/A

PCR ID: 1393

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Neutralizes venom from Bothrops alternatus, Bothrops newiedii, Bothropos jararacá and Bothrops jararacussu (vipers Yarará grande or de la cruz, Yarará chica, Yararaca and Yararacusú respectively)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Instituto Nacional de Producción de Biológicos (ANLIS)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bothrops alternatus; Bothrops ammodytoides; Bothrops jararaca; Bothrops jararacussu; Bothrops moojeni; Bothrops neuwiedi
Snake species *(Sources: other)*	**B. alternatus, B. newiedii, B. jararaca and B. jararacussu**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Argentina
Regions	South America

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: Other)*	
Snake family	
Risk category	

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Argentina

Region of use: South America

WHO prequalification: No

Europe

Anti-viper antivenom (Microgen and Ministry of Health, Russian Federation)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1388

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Vipera berus (Cross adder, European adder, Northern adder)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Anti-viper (anti-adder) antivenom was developed by the Federal State Company for Immunobiological Medicines, Microgen (Moscow, Russia), and registered in the Russian Federation for treatment of Vipera berus/common European adder envenoming (https://www.microgen.ru/products/syvorotki/syvorotka-protiv-yada-gadyuki-obyknovennoy-loshadinaya-ochishchennaya-kontsentrirovannaya-zhidkaya/). It is a clear or slightly opalescent liquid with a yellowish tint, without sediment. (https://www.microgen.ru/products/syvorotki/syvorotka-protiv-yada-gadyuki-obyknovennoy-loshadinaya-ochishchennaya-kontsentrirovannaya-zhidkaya/). It is comprised of F(ab')2 immunoglobulins obtained from the blood of hyperimmunized horses, and has been shown to effectively inhibit the PLA2 toxin responsible for the haemorrhagic symptoms caused by systemic Vipera berus envenomation (https://pubmed.ncbi.nlm.nih.gov/30717298/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Federal State Company for Immunobiological Medicines, Microgen (Moscow, Russia)

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/30717298/https://pubmed.ncbi.nlm.nih.gov/30717298/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Vipera berus
Snake species *(Sources: other)*	**Vipera berus (Cross adder, European adder, Northern adder)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Russia
Regions	Eastern Europe

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Vipera berus (Cross adder, European adder, Northern adder)	Vipera berus (Cross adder, European adder, Northern adder)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: PLA2s

Syndromic profiles: Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Russia

Region of use: Europe

WHO prequalification: No

Antiviperine sera (National Center of Infectious and Parasitic Diseases, Bulgaria)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1384

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Vipera ammodytes (Nose-horned viper, Sand viper); Vipera aspis (Asp viper); Vipera berus (Cross adder, European adder, Northern adder); Vipera ursinii (Meadow viper, Orsini's viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Bulgarian Antiviperine sera was developed by the National Center of Infectious and Parasitic Diseases, Bulgaria, and manufactured by the state-owned company - Bul Bio (https://bulbio.com/en/serums.html). Raised from the venom of Vipera ammodytes (Nose-horned viper, Sand viper), it is the only type of anti-snake serum in Bulgaria and it is indicated for the treatment of systemic envenomation caused by the venoms of Vipera ammodytes (Nose-horned viper, Sand viper); Vipera aspis (Asp viper); Vipera berus (Cross adder, European adder, Northern adder); and Vipera ursinii (Meadow viper, Orsini's viper) (http://www.antivenoms.toxinfo.med.tum.de/productinfo/MONOVALENT.html)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: National Center of Infectious and Parasitic Diseases, Bulgaria

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Vipera ammodytes; Vipera aspis; Vipera berus; Vipera ursinii
Snake species *(Sources: other)*	**Vipera ammodytes (Nose-horned viper, Sand viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Bulgaria
Regions	Eastern Europe

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Vipera ammodytes (Nose-horned viper, Sand viper); Vipera aspis (Asp viper); Vipera berus (Cross adder, European adder, Northern adder); Vipera ursinii (Meadow viper, Orsini's viper)	Vipera ammodytes (Nose-horned viper, Sand viper); Vipera aspis (Asp viper); Vipera berus (Cross adder, European adder, Northern adder); Vipera ursinii (Meadow viper, Orsini's viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Bulgaria

Region of use: Europe

WHO prequalification: No

European viper venom antiserum (Imunološki Zavod (Institute of Immunology), Croatia)

Alternative name(s): Antitoksin za otrov europskih zmija (konjski)

Chemical name: N/A

CAS number: N/A

PCR ID: 1330

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Vipera ammodytes (Nose-horned viper, Sand viper); Vipera aspis (Asp viper); Vipera berus (Cross adder, European adder, Northern adder); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Antitoxin for the venom of European snakes (equine) is used only for treatment after the bite of snakes of the family Viperidae. The polyvalent antitoxin neutralizes the absorbed venom of the snake. Each 1ml of the antivenom contains F(ab)2 fragments of equine immunoglobulin molecules for specific neutralization not less than: 100 LD50 poisons of V. ammodytes; 100 LD50 poisons of V. aspis; 50 LD50 poisons of V. berus; 50 LD50 poisons of V. lebetina and 50 LD50 poisons of V. xanthina, according to preclinical studies using mice (https://halmed.hr/upl/lijekovi/SPC/Antitoksin-za-otrov-europskih-zmija-konjski-SPC.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Imunološki Zavod, Croatia

Preclinical results status: Available

Preclinical sources: https://halmed.hr/upl/lijekovi/SPC/Antitoksin-za-otrov-europskih-zmija-konjski-SPC.pdf

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Vipera ammodytes
Snake species *(Sources: other)*	**Vipera ammodytes (Nose-horned viper, Sand viper); Vipera aspis (Asp viper); Vipera berus (Cross adder, European adder, Northern adder); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Croatia
Regions	Central Europe

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Macrovipera lebetina; Montivipera raddei; Montivipera xanthina; Vipera aspis; Vipera berus; Vipera ursinii
Snake species *(Sources: Other)*	Vipera ammodytes (Nose-horned viper, Sand viper); Vipera aspis (Asp viper); Vipera berus (Cross adder, European adder, Northern adder); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper)	Vipera ammodytes (Nose-horned viper, Sand viper); Vipera aspis (Asp viper); Vipera berus (Cross adder, European adder, Northern adder); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Croatia

Region of use: Europe

WHO prequalification: No

Polisera (Vetal Serum ve Biyolojik Ürünler Üretim Sanayi Tic. A.Ş, Turkey)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1339

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper); Vipera ammodytes (Nose-horned viper, Sand viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Polisera is polyvalent antivenom developed by the Turkish Vetal Sera and Biological Products Production and Manufacturing Company, from the blood of horses immunised with the venom of Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper); Vipera ammodytes (Nose-horned viper, Sand viper), all of which are snakes common in Turkey (http://www.vetalserum.com.tr/en/urunler/polisera-snake-antiserum). It is available as a clear, almost colourless or light yellow injectable solution with a light smell. According to the manufacturer, preclinical studies in mice and guinea pigs have demonstrated its efficacy and safety (http://www.vetalserum.com.tr/en/urunler/polisera-snake-antiserum).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Vetal Sera and Biological Products Production and Marketing Company, Turkey

Preclinical results status: Available

Preclinical sources: http://www.vetalserum.com.tr/en/urunler/polisera-snake-antiserumhttps://dergipark.org.tr/en/download/article-file/1105235

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Macrovipera lebetina; Montivipera xanthina; Vipera ammodytes
Snake species *(Sources: other)*	**Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper); Vipera ammodytes (Nose-horned viper, Sand viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Turkey
Regions	Eastern Europe

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper); Vipera ammodytes (Nose-horned viper, Sand viper)	Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper); Vipera ammodytes (Nose-horned viper, Sand viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Turkey

Region of use: Europe

WHO prequalification: No

Viekvin (Institute of Virology, Vaccine and Sera, TORLAK, Serbia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1333

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Vipera ammodytes (Nose-horned viper, Sand viper); Vipera berus (Cross adder, European adder, Northern adder)

Route of administration: Intramuscular; Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

VIEKVIN® is an aqueous solution for injection containing antibodies, i.e. antitoxic globulins -F(ab)2 fragments that have the power of neutralising the venom of European vipers (long-nosed viper and common European adder). Specific immunoglobulins are obtained from the plasma of healthy horses immunised against the long-nosed viper venom (Vipera ammodytes) by the fraction precipitation method (ammonium sulphate) and enzyme treatment (pepsin). VIEKVIN® is indicated for the therapy after bites of vipers of the genus Vipera (long-nosed viper, common European adder). Viper venom antiserum (equine), VIEKVIN®, is not effective against venoms of other snakes (http://www.torlakinstitut.com/pdf/Viekvin-en.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Institute of Virology, Vaccine and Sera "TORLAK", Serbia

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Macrovipera lebetina; Montivipera xanthina; Vipera ammodytes; Vipera aspis; Vipera berus
Snake species *(Sources: other)*	**Vipera ammodytes (Nose-horned viper, Sand viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Serbia
Regions	Eastern Europe

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Vipera ammodytes (Nose-horned viper, Sand viper); Vipera berus (Cross adder, European adder, Northern adder)	Vipera ammodytes (Nose-horned viper, Sand viper); Vipera berus (Cross adder, European adder, Northern adder)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Serbia

Region of use: Europe

WHO prequalification: No

Viper venom antitoxin (BIOMED Wytwornia Surowic i Szczepionek, Poland)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1386

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Vipera berus (Cross adder, European adder, Northern adder)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Viper venom antitoxin contains specific equine F(ab')2 immunoglobulin fragments that bind venom of Vipera berus, thus neutralising its toxicity. It was raised from horses hyperimmunised with the venom of the European common adder, and it is packaged in ampoules contained clear, pale yellow or colorless solutions (https://www.biodrug.sk/docs/en_viper_venom.pdf). In a comparative preclinical study of this antivenom and others including - Zagreb antivenom, Viperfav, ViperaTAB and Inoserp Europe, the BIOMED product was shown to have effectiveness limited to V. berus, and was ineffective against Vipera ammodyte (https://pubmed.ncbi.nlm.nih.gov/33805701/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: BIOMED (Wytwornia Surowic i Szczepionek)

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/33805701/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Vipera berus
Snake species *(Sources: other)*	**Vipera berus (Cross adder, European adder, Northern adder)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Poland
Regions	Central Europe

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Vipera berus (Cross adder, European adder, Northern adder); Vipera ammodytes (Nose-horned viper, Sand viper)	Vipera berus (Cross adder, European adder, Northern adder)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Poland

Region of use: Europe

WHO prequalification: No

ViperaTAb (MicroPharm Ltd, United Kingdom)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1387

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Fab immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

ViperaTAb® is a monospecific ovine antivenom raised against the venom of V. berus and is manufactured by MicroPharm Limited in the United Kingdom (https://micropharm.co.uk/products/current_products/). The antivenom is made from hyper-immunised sheep serum and consists of ovine Fab fragments which are cleaved from intact IgG molecules during manufacturing. Subsequently, the Fab fragments are affinity purified using column chromatography, meaning that all of the antibodies present in ViperaTAb® are specific to snake venom toxins,. A prospective audit of ViperaTAb use was conducted from March 2016 until November 2020 by the UK National Poison Information Service (NPIS). ViperaTAb antivenom appears to be effective and safe and should be administered as soon as possible for patients meeting clinical criteria (https://pubmed.ncbi.nlm.nih.gov/33720783/).It has also been tested in patients envenomed by V. a. ammodytes venom, and found that ViperaTAb® reduces moderate swelling and temporarily improves systemic effects, except neurological symptoms (https://pubmed.ncbi.nlm.nih.gov/28092984/). Other immunological experiments revealed that ViperaTAb® (anti-V. berus) exhibits substantial cross-reactivity with the venoms of other Vipera snake species. Notably, ViperaTAb® neutralised the lethality induced by V. berus, V. aspis, V. ammodytes and V. latastei venoms in vivo and at much higher levels than those outlined by regulatory pharmacopoeia guidelines.(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4147594/pdf/toxins-06-02471.pdf)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: MicroPharm Ltd

Preclinical results status: Available

Preclinical sources: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4147594/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Vipera berus
Snake species *(Sources: other)*	**Vipera berus (European common adder)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Eastern Europe; Central Europe; Western Europe

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of sheep

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Vipera aspis (European asp); Vipera ammodytes (horned viper); Vipera berus (European adder); Vipera latastei (snub-nosed viper); Vipera ursinii (meadow viper); Macrovipera lebetina (blunt-nosed viper); Montivipera xanthina (rock viper)	Vipera berus (European adder); Vipera aspis (European asp); Vipera ammodytes (horned viper); Vipera latastei (snub-nosed viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: United Kingdom

Region of use: Europe

WHO prequalification: No

VIPERFAV (MicroPharm Ltd, United Kingdom)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1385

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; European vipers

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2°C - 8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

VIPERFAV® is an antivenom made from Immunoglobulin F(ab')2 fragments of equine origin (solution for dilution for infusion). Indicated for the treatment of envenomation (grade II or III) by European vipers (Vipera aspis, Vipera berus, Vipera ammodytes). VIPERFAV is a preparation containing equine immunoglobulin F(ab')2 fragments which have the property of neutralising the venom of three species of vipers: Vipera aspis, Vipera berus, Vipera ammodytes. These equine immunoglobulin F(ab')2 fragments fix the venom antigens present in the blood in the form of inactive F(ab')2-antigen complexes, reducing the level of free venom in the blood (https://micropharm.co.uk/products/current_products/). The product has a Marketing Authorisation (34009 562 154 09) granted by ANSM.The venoms are purchased from Latoxan in France. The berus venom is from Russia whilst the other two are from snakes kept in France. VIPERFAV is approved in France and distributed by Inresa Pharma. VIPERFAV unofficially used in other European countries and is distributed by Flynn Pharma. A prospective case review study of viper envenomings treated with Viperfav™ was compiled by the Angers Poisons Centre. A single infusion of Viperfav™ (one vial) was effective whatever the grade of envenomation, and multiple doses did not improve the outcome. Viperfav™ was most effective when given soon (< 10 h) after envenoming.(https://pubmed.ncbi.nlm.nih.gov/22372786/).para(https://pubmed.ncbi.nlm.nih.gov/28092984/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: MicroPharm Ltd

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/9519157/

Evidence of clinical trials? Yes

Phase: N/A, (Status: Unknown, -): *N/A* (CT number: N/A, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Vipera aspis (European asp); Vipera berus (common European adder); Vipera ammodytes (horned viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	France; Russia
Regions	Eastern Europe; Western Europe

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Vipera aspis (European asp); Vipera berus (common European adder); Vipera ammodytes (horned viper)	Vipera aspis (European asp); Vipera berus (common European adder); Vipera ammodytes (horned viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: France

Region of use: Europe

WHO prequalification: No

North Africa

Favirept (MicroPharm UK, previously Sanofi-Pasteur, France)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1956

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: B. arietans, C. cerastes, D. deserti, E. leucogaster, M. deserti, N. haje, N. nigricollis

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2°C - 8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Favirept was manufactured by Sanofi Pasteur, France. This was specific for mostly North African snakes (Bitis arietans, Cerastes cerastes, Echis leucogaster, Macrovipera deserti, Naja haje, and Naja nigricollis), but is no longer manufactured. (https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/macrovipera-lebetina)In 2018, MicroPharm Limited acquired Sanofi Pasteur's antivenom equine immunoglobulin product range comprising Viperfav®, Bothrofav® Scorpifav®, Fav-Afrique® and Favirept®. The transaction comprised the transfer of the intangible and some tangible assets to MicroPharm. Over the next three years MicroPharm and Sanofi Pasteur transfered the manufacture of Viperfav, Bothrofav and Scorpifav to MicroPharm's manufacturing facilities in West Wales. MicroPharm said it would seek to re-launch Fav-Afrique and Favirept to the African and Middle East markets where there is an unmet need for safe and effective antivenoms tailored to these regions. (https://micropharm.co.uk/news/2018/1/acquisition_of_sanofi_pasteurs_equine_antivenom_immunoglobulin_products)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Inactive

Developers/investigators: Sanofi Pasteur; MicroPharm Ltd

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Bitis arietans (puff adder); Crotalus cerastes (sidewinder); Daboia deserti; E. leucogaster, M. deserti (desert viper); N. haje (Egyptian cobra); N. nigricollis (black-necked spitting cobra)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Angola; Benin; Burundi; Botswana; Burkina Faso; Cameroon; Central African Republic; Chad; Congo; Cote D`Ivoire (Ivory Coast); Democratic Republic of Congo; Djibouti; Eritrea; Eswatini (Swaziland); Ethiopia; Gabon; Gambia; Ghana; Guinea; Guinea-Bissau; Kenya; Lesotho; Liberia; Malawi; Mali; Mauritania; Morocco; Mozambique; Namibia; Niger; Nigeria; Oman; Rwanda; Saudi Arabia; Senegal; Sierra Leone; Somalia; Senegal; South Africa; South Sudan; Sudan; Togo; Uganda; Tanzania; Yemen; Zambia; Zimbabwe; Algeria; Egypt; Israel; Libya; Occupied Palestinian Territory; Tunisia; Togo
Regions	West Africa; Central Africa; Southern Africa; East Africa; North Africa; Middle East

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis arietans (puff adder); Crotalus cerastes (sidewinder); Daboia deserti; E. leucogaster, M. deserti (desert viper); N. haje (Egyptian cobra); N. nigricollis (black-necked spitting cobra)	Bitis arietans (puff adder); Crotalus cerastes (sidewinder); Daboia deserti; E. leucogaster, M. deserti (desert viper); N. haje (Egyptian cobra); N. nigricollis (black-necked spitting cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Discontinued

Approval status: Approved

Approving authority: NRA

Region of use: North Africa

WHO prequalification: No

Gamma-Vip (Institut Pasteur de Tunis, Tunisia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1328

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The commercial antiviperid antivenom from Institut Pasteur de Tunis (Gamma-VIP) was generated by hyperimmunization of horses with a mixture of Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper) found in Tunisia (http://www.pasteur.tn/index.php?option=com_content&view=article&id=161&Itemid=199). The antivenom consists of F(ab)2 fragments generated by digestion with pepsin of ammonium sulphate-precipitated IgG molecules. It has been shown in a preclinical study to be effective against most toxins found in the venoms of both snake species, but with weak activity against the PLA2 toxin. representing a potentially fatal therapeutic weakness (https://pubmed.ncbi.nlm.nih.gov/22387316/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Institut Pasteur de Tunis

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/22387316/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Cerastes cerastes; Macrovipera lebetina
Snake species *(Sources: other)*	**Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Tunisia
Regions	North Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper)	Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Tunisia

Region of use: North Africa

WHO prequalification: No

Inoserp MENA (INOSAN BIOPHARMA S. A., Spain)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1342

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Middle Eastern and North African snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 8°C - 30°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Inoserp MENA is a polyvalent equine antivenom specifically indicated for the treatment of sub- Middle East and North African snake bites. It is a sterile, highly purified lyophilized preparation of equine F(ab´)2 immunoglobulin fragments neutralizing with high specificity the venoms of the following species: Viperidae: Bitis arietans, Cerastes cerastes, Cerastes gasperettii, Cerastes vipera, Daboia deserti, Daboia mauritanica, Daboia palaestinae, Echis carinatus sochureki, Echis coloratus, Echis khosatzkii, Echis leucogaster, Echis megalocephalus, Echis omanensis, Echis pyramidum, Macrovipera lebetina obtusa, Macrovipera lebetina transmediterranea, Macrovipera lebetina turanica, Montivipera bornmuelleri, Montivipera raddei kurdistanica, Pseuocerastes fieldi, Pseudocerastes persicus, Vipera latastei and Elapidae: Naja haje, Naja nubiae, Naja pallida and Walterinnesia aegyptia (https://inosanbiopharma.com/assets/Abbreviated-Prescribing-Information-ISME-15-04-2020_INOSERP_MENA.pdf). Inosan states: there are no preclinical safety studies performed with INOSERP. They have clinically evaluated the Inoserp Pan-Africa product which has the same active substance and preparation as the MENA product. Both antivenoms are composed of F(ab')2 fragments obtained from specific immunoglobulins G (IgG) against venom components just for different geographical regions.
(https://ansm.sante.fr/uploads/2020/12/11/6c457c21ae6c424c0a48b5a3720311a8.pdf)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: INOSAN Biopharma SA

Preclinical results status: Available

Preclinical sources:
https://ansm.sante.fr/uploads/2020/12/11/6c457c21ae6c424c0a48b5a3720311a8.pdf

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Cerastes cerastes; Echis leucogaster; Macrovipera lebetina; Montivipera raddei; Naja haje; Naja nigricollis; Naja pallida; Pseudocerastes fieldi; Pseudocerastes persicus; Walterinnesia aegyptia
Snake species *(Sources: other)*	**Bitis arietans (puff adder); Cerastes cerastes (Saharan horned viper); Naja haje (Egyptian cobra); Macrovipera lebetina obtusa (West-Asian blunt-nosed viper); Vipera palestinae (Palestine viper); Naja pallida (red spitting cobra); Naja nigricollis (black-necked spitting cobra); Walterinesia aegyptia (desert cobra); Echis leucogaster (white-bellied carpet viper); Macrovipera deserti (desert viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	North Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Cerastes gasperettii; Daboia deserti; Daboia mauritanica; Daboia palaestinae; Echis carinatus; Echis coloratus; Echis khosatzkii; Echis megalocephalus; Echis omanensis; Echis pyramidum; Naja nubiae; Vipera latastei
Snake species *(Sources: Other)*	Bitis arietans (puff adder); Cerastes cerastes (Saharan horned viper); Cerastes gasperettii (Arabian horned viper); Cerastes vipera (Sahara sand viper); Daboia deserti; Daboia mauritanica (Moorish Viper); Daboia palaestinae (Palestine viper); Echis carinatus sochureki (Sochurek's saw-scaled viper); Echis coloratus (painted saw-scaled viper); Echis khosatzkii, Echis leucogaster (white-bellied carpet viper); Echis megalocephalus (big-headed carpet viper); Echis omanensis (Oman saw-scaled viper); Echis pyramidum (Northeast African carpet viper); Macrovipera lebetina obtusa (West-Asian blunt-nosed viper); Macrovipera lebetina transmediterranea; Macrovipera lebetina turanica (Turan blunt-nosed viper); Montivipera bornmuelleri (Lebanon viper); Montivipera raddei kurdistanica (Armenian viper); Pseuocerastes fieldi (Field's horned viper); Pseudocerastes persicus (Persian horned viper); Vipera latastei (Lataste's viper); Naja haje (Egyptian cobra); Naja nubiae (Nubian spitting cobra); Naja pallida (red spitting cobra); Walterinnesia aegyptia (desert cobra)	Bitis arietans (puff adder); Cerastes cerastes (Saharan horned viper); Cerastes gasperettii (Arabian horned viper); Cerastes vipera (Sahara sand viper); Daboia deserti; Daboia mauritanica (Moorish Viper); Daboia palaestinae (Palestine viper); Echis carinatus sochureki (Sochurek's saw-scaled viper); Echis coloratus (painted saw-scaled viper); Echis khosatzkii, Echis leucogaster (white-bellied carpet viper); Echis megalocephalus (big-headed carpet viper); Echis omanensis (Oman saw-scaled viper); Echis pyramidum (Northeast African carpet viper); Macrovipera lebetina obtusa (West-Asian blunt-nosed viper); Macrovipera lebetina transmediterranea; Macrovipera lebetina turanica (Turan blunt-nosed viper); Montivipera bornmuelleri (Lebanon viper); Montivipera raddei kurdistanica (Armenian viper); Pseuocerastes fieldi (Field's horned viper); Pseudocerastes persicus (Persian horned viper); Vipera latastei (Lataste's viper); Naja haje (Egyptian cobra); Naja nubiae (Nubian spitting cobra); Naja pallida (red spitting cobra); Walterinnesia aegyptia (desert cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Mexico; Chad; Morocco; Netherlands; Israel; Belgium; United Kingdom; United States of America

Region of use: North Africa

WHO prequalification: No

IPAVIP Antiviperin Sera (Institut Pasteur d'Algerie, Algeria)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1329

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper)

Route of administration: Intravenous

Ig format: Unknown

Ig final product type/preparation: Unknown

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The IPAVIP Antiviperin Serum developed by the Institut Pasteur d'Algerie is a bivalent antivenom obtained from the immunoglobulin-containing blood of horses hyperimmunized with the venoms of Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper) (https://www.pasteur.dz/fr/directions/d-p-direction-de-la-production) (http://www.antivenoms.toxinfo.med.tum.de/productinfo/ANTI-VIPERIN__BIVALENT_.html)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Institut Pasteur d'Algerie, Algeria

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Cerastes cerastes; Macrovipera lebetina
Snake species *(Sources: other)*	**Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Algeria
Regions	North Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper)	Cerastes cerastes (Horned viper, Saharan horned viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Algeria

Region of use: North Africa

WHO prequalification: No

Polyvalent Anti-Snake Serum (Egyptian Organisation for Biological Products and Vaccines (VACSERA), Egypt)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1331

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Cerastes cerastes (Horned viper, Saharan horned viper); Cerastes vipera (Sahara sand viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja mossambica (Mozambique spitting cobra); Naja nigricollis (Black-necked spitting cobra); Naja oxiana (Central Asian cobra, Transcaspian cobra); Pseudocerastes persicus (Persian horned viper, Shfifon); Vipera ammodytes (Nose-horned viper, Sand viper); Vipera palestinae (Palestine viper); Walterinnesia aegyptia (Desert cobra, Peten); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The VACSERA polyvalent snake antiserum is a polyvalent antivenom containing equine immunoglobulin fragment F(ab')2, derived from the plasma of healthy equines, hyper immunized with snake venom (https://pubmed.ncbi.nlm.nih.gov/32817682/). It is indicated for neutralising the venom of multiple snakes belonging to the Viperidae and Elapidae families of snakes, including Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Cerastes cerastes (Horned viper, Saharan horned viper); Cerastes vipera (Sahara sand viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja mossambica (Mozambique spitting cobra); Naja nigricollis (Black-necked spitting cobra); Naja oxiana (Central Asian cobra, Transcaspian cobra); Pseudocerastes persicus (Persian horned viper, Shfifon); Vipera ammodytes (Nose-horned viper, Sand viper); Vipera palestinae (Palestine viper); Walterinnesia aegyptia (Desert cobra, Peten) and Echis coloratus (Burton's carpet viper, Palestine saw scaled viper (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6615628/).It is approved for use in Egypt and according to manufacturers' recommendations (VACSERA), the initial recommended dose of antivenom is 3–5 vials, intravenous infusion over 1 h. Additional antivenom doses may be repeated on the basis of the clinical condition. While dosing recommendations are vague, up to 10 vials can be administered, according to the manufacturer's recommendation

(http://egyvac.vacsera.com/egyvacProfile.pdf), and it has been shown by clinical case report, to be effective in neutralising neurotoxic, haemorrhagic and cytotoxic effects of systemic envenomation (https://doi.org/10.4103/ami.ami_48_17).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Egyptian Organisation for Biological Products and Vaccines (VACSERA)

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/12503876/https://pubmed.ncbi.nlm.nih.gov/12503876/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7462309/https://doi.org/10.4103/ami.ami_48_17https://pubmed.ncbi.nlm.nih.gov/27476228/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Cerastes cerastes; Naja haje; Naja nubiae
Snake species *(Sources: other)*	**Cerastes cerastes (Horned viper, Saharan horned viper); Naja haje (Egyptian cobra) and Naja nubiae**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Egypt
Regions	North Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Bitis arietans; Bitis gabonica; Daboia palaestinae; Echis coloratus; Macrovipera lebetina; Montivipera xanthina; Naja melanoleuca; Naja mossambica; Naja nigricollis; Naja oxiana; Naja pallida; Pseudocerastes fieldi; Vipera ammodytes

	Tested in	Effective against (any efficacy data)
Snake species *(Sources: Other)*	Naja guineensis (Black forest cobra); Naja peroescobari (São Tomé Cobra); Naja savannula (West African Banded Cobra); Naja subfulva (Brown Forest Cobra)Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Cerastes cerastes (Horned viper, Saharan horned viper); Cerastes vipera (Sahara sand viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja mossambica (Mozambique spitting cobra); Naja nigricollis (Black-necked spitting cobra); Naja oxiana (Central Asian cobra, Transcaspian cobra); Naja pallida (Red spitting cobra); Pseudocerastes persicus (Persian horned viper, Shfifon); Vipera ammodytes (Nose-horned viper, Sand viper); Vipera palestinae (Palestine viper); Walterinnesia aegyptia (Desert cobra, Peten); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Echis carinatus (Saw-scaled viper); Naja nivea (Cape cobra)	Manufacturer label claim of paraspecificity: Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Cerastes cerastes (Horned viper, Saharan horned viper); Cerastes vipera (Sahara sand viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja mossambica (Mozambique spitting cobra); Naja nigricollis (Black-necked spitting cobra); Naja oxiana (Central Asian cobra, Transcaspian cobra); Naja pallida (Red spitting cobra); Pseudocerastes persicus (Persian horned viper, Shfifon); Vipera ammodytes (Nose-horned viper, Sand viper); Vipera palestinae (Palestine viper); Walterinnesia aegyptia (Desert cobra, Peten); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Echis carinatus (Saw-scaled viper)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding),Cytotoxic (tissue damage),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Egypt

Region of use: North Africa

WHO prequalification: No

Polyvalent Anti-Vipers Serum (Egyptian Organisation for Biological Products and Vaccines (VACSERA), Egypt)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1332

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Cerastes cerastes (Horned viper, Saharan horned viper); Cerastes vipera (Sahara sand viper); Pseudocerastes fieldi (Field's horned viper, Shfifon); Echis carinatus Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Vipera ammodytes (Nose-horned viper, Sand viper); Montivipera xanthina (Coastal viper, Ottoman viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Polyvalent viper antiserum is a polyvalent antivenom containing equine immunoglobulin fragment F(ab')2, derived from the plasma of healthy equines, hyper immunized with viper snake venom. It is indicated for neutralising the venom of multiple snakes belonging to the Viperidae family, including: Cerastes cerastes (Horned viper, Saharan horned viper); Cerastes vipera (Sahara sand viper); Pseudocerastes fieldi (Field's horned viper, Shfifon); Echis carinatus Echis carinatus (Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Vipera ammodytes (Nose-horned viper, Sand viper); Montivipera xanthina (Coastal viper, Ottoman viper) (http://egyvac.vacsera.com/egyvacProfile.pdf).It is approved for use in Egypt and according to manufacturers' recommendations (VACSERA), the initial recommended dose of antivenom is 3–5 vials, intravenous infusion over 1 h. Additional antivenom doses may be repeated on the basis of the clinical condition. Although dosing recommendations are vague, up to 10 vials can be administered (http://egyvac.vacsera.com/egyvacProfile.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Egyptian Organisation for Biological Products and Vaccines (VACSERA)

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Cerastes cerastes; Echis coloratus; Echis pyramidum
Snake species *(Sources: other)*	**Cerastes cerastes (Horned viper, Saharan horned viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Echis pyramidum (East African carpet viper, Egyptian saw scaled viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Egypt
Regions	North Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Macrovipera lebetina; Montivipera xanthina; Pseudocerastes fieldi; Vipera ammodytes
Snake species *(Sources: Other)*	Cerastes cerastes (Horned viper, Saharan horned viper); Cerastes vipera (Sahara sand viper); Pseudocerastes fieldi (Field's horned viper, Shfifon); Echis carinatus (Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Vipera ammodytes (Nose-horned viper, Sand viper); Montivipera xanthina (Coastal viper, Ottoman viper)	Manufacturer label claim of paraspecificity: Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera xanthina (Coastal viper, Ottoman viper); Pseudocerastes fieldi (Field's horned viper, Shfifon); Vipera ammodytes (Nose-horned viper, Sand viper)Cerastes cerastes (Horned viper, Saharan horned viper); Cerastes vipera (Sahara sand viper); Pseudocerastes fieldi (Field's horned viper, Shfifon); Echis carinatus (Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Vipera ammodytes (Nose-horned viper, Sand viper); Montivipera xanthina (Coastal viper, Ottoman viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Egypt

Region of use: North Africa

WHO prequalification: No

Snake Venom Antiserum Afriven (VINS Bioproducts Ltd, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1356

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

AFRIVEN is a sterile preparation containing equine immunoglobulin fragments F (ab') 2. Freeze dried powder is reconstituted in 10ml of sterile water for injection supplied along with the vial. Each vial of AFRIVEN is effective against the snake venoms of VIPERIDAE: Echis ocellatus, Echis leucogaster, Echis pyramidum, Bitis arientans, Bitis rhinoceros, Bitis nasicornis,, Bitis gabonica and ELAPIDAE: Dendroaspis polylepis, Dendroaspis viridis, Dendroaspis angusticeps, Dendroaspis jamesoni, Naja nigricollis, Naja melanoleuca, Naja haje, Naja pallida, Naja nivea, Naja senegalensis, Naja annulifera, Naja mossambica, Naja Ashei. (https://vinsbio.in/afriven/)(https://pubmed.ncbi.nlm.nih.gov/32817682/; https://pubmed.ncbi.nlm.nih.gov/29045429/; https://pubmed.ncbi.nlm.nih.gov/27886134/; https://pubmed.ncbi.nlm.nih.gov/27377229/; https://pubmed.ncbi.nlm.nih.gov/31233536/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VINS Bioproducts

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**E. ocellatus (West African carpet viper); E. leucogaster (white-bellied carpet viper); E. pyramidum (Northeast African carpet viper); B. arientans (puff adder); Bitis rhinoceros (West African gaboon viper); Bitis nasicornis (butterfly viper); B. gabonica (Gaboon viper); D. polylepis (black mamba); D. viridis (green mamba); D. angusticeps (eastern green mamba); D. jamesoni; N. nigricollis, N. melanoleuca, N. haje, N. pallida, N. nivea, N. senegalensis, N. annulifera, N. mossambica, N. Ashei**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	---E. ocellatus (West African carpet viper); E. leucogaster (white-bellied carpet viper); E. pyramidum (Northeast African carpet viper); B. arientans (puff adder); Bitis rhinoceros (West African gaboon viper); Bitis nasicornis (butterfly viper); B. gabonica (Gaboon viper); D. polylepis (black mamba); D. viridis (green mamba); D. angusticeps (eastern green mamba); D. jamesoni; N. nigricollis, N. melanoleuca, N. haje, N. pallida, N. nivea, N. senegalensis, N. annulifera, N. mossambica, N. Ashei	---E. ocellatus (West African carpet viper); E. leucogaster (white-bellied carpet viper); E. pyramidum (Northeast African carpet viper); B. arientans (puff adder); Bitis rhinoceros (West African gaboon viper); Bitis nasicornis (butterfly viper); B. gabonica (Gaboon viper); D. polylepis (black mamba); D. viridis (green mamba); D. angusticeps (eastern green mamba); D. jamesoni; N. nigricollis, N. melanoleuca, N. haje, N. pallida, N. nivea, N. senegalensis, N. annulifera, N. mossambica, N. Ashei
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: North Africa

WHO prequalification: No

Snake Venom Antitoxin - Menaven (VINS Bioproducts Ltd, India)

Alternative name(s): BioSnake

Chemical name: N/A

CAS number: N/A

PCR ID: 1357

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous; Intramuscular

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Snake venom antitoxin polyvalent is prepared from purified plasma of healthy horses, which have been hyperimmunized against venoms of the most dangerous snakes mentioned below. The antitoxin is purified from whole equine immune serum by pepsin digestion. It is intended for either intramuscular injection or intravenous infusion according to the severity of the condition.Menaven neutralises the snake venom from Naja haje, Naja nigricollis Cerastes and Cerastes. It has paraspecificity for: Walterinnesia aegyptia, Bitis gabonica (East, Central and Southern Africa), Echis carinatus, Macrovipera xanthina, Macrovipera lebetina, Vipera ammodytes, Cerastes vipera, Naja naje oxiana, Naja mossambica, Naja melanoleuca, Bitis arietans and Vipera palestinae (https://vinsbio.in/menaven/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VINS Bioproducts

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Cerastes cerastes; Naja haje; Naja nigricollis
Snake species *(Sources: other)*	**Naja haje (Egyptian cobra); Naja nigricollis (Black-necked spitting cobra); Cerastes Cerastes (Horned desert viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	North Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Walterinnesia aegyptia (desert cobra); Bitis gabonica (Gaboon viper); Echis carinatus (saw-scaled viper); Macrovipera xanthina (rock viper); Macrovipera lebetina (blunt-nosed viper); Vipera ammodytes (horned viper); Cerastes vipera (Sahara sand viper); Naja naje oxiana (Central Asian cobra); Naja mossambica (Mozambique spitting cobra); Naja melanoleuca (forest cobra); Bitis arietans (puff adder); Vipera palestinae (Palestine viper)	Walterinnesia aegyptia (desert cobra); Bitis gabonica (Gaboon viper); Echis carinatus (saw-scaled viper); Macrovipera xanthina (rock viper); Macrovipera lebetina (blunt-nosed viper); Vipera ammodytes (horned viper); Cerastes vipera (Sahara sand viper); Naja naje oxiana (Central Asian cobra); Naja mossambica (Mozambique spitting cobra); Naja melanoleuca (forest cobra); Bitis arietans (puff adder); Vipera palestinae (Palestine viper)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Jordan

Region of use: North Africa

WHO prequalification: No

Sub-Saharan Africa

Anti Snake Venom Serum Central Africa - 6 (Biological E Limited, India)

Alternative name(s): BEAFRIQUE-6, I.H.S

Chemical name: N/A

CAS number: N/A

PCR ID: 1359

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Anti Snake Venom Serum - Central Africa (6) is a polyvalent, Equine F(ab')2 antivenom also branded as BEAFRIQUE-6 It has an indication of passive immunization against African snakes and comes in Liquid & Lyophilized 10 mL Vial. (https://www.biologicale.com/pdf/Product_Sera_List.pdf)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Biological E Limited

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Cerastes cerastes; Daboia deserti; Echis leucogaster; Naja haje; Naja nigricollis
Snake species *(Sources: other)*	**Bitis arietans (puff adder); Echis leucogaster (white-bellied carpet viper); Naja haja (Egyptian cobra); Naja nigricollis (black-necked spitting cobra); Cerastes cerastes (Saharan horned viper); Macrovipera deserti (desert viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Central Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis arietans (puff adder); Echis leucogaster (white-bellied carpet viper); Naja haja (Egyptian cobra); Naja nigricollis (black-necked spitting cobra); Cerastes cerastes (Saharan horned viper); Macrovipera deserti (desert viper)	Bitis arietans (puff adder); Echis leucogaster (white-bellied carpet viper); Naja haja (Egyptian cobra); Naja nigricollis (black-necked spitting cobra); Cerastes cerastes (Saharan horned viper); Macrovipera deserti (desert viper)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India

Region of use: Sub-Saharan Africa

WHO prequalification: No

Anti Snake Venom Serum Monovalent Echis ocellatus (Biological E Limited, India)

Alternative name(s): BEAFRIQUE-1

Chemical name: N/A

CAS number: N/A

PCR ID: 1417

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Echis ocellatus (Ocellated carpet viper, West African carpet viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Both

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The ANTI SNAKE VENOM SERUM MONOVALENT - Echis ocellatus also known by the trade name BEAFRIQUE-1 is a monovalent antivenom targeted at the venom of African Echis ocellatus. It is manufactured by Biological E, India and consists of F(ab)'2 immunoglobulin fragments derived from the plasma of horses immunised with Echis ocellatus venom (https://www.biologicale.com/pdf/Product_Sera_List.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Biological E Limited

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis ocellatus
Snake species *(Sources: other)*	**Echis ocellatus (Ocellated carpet viper, West African carpet viper)**
Snake family	**Viperidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	
Regions	West Africa

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Echis ocellatus (Ocellated carpet viper, West African carpet viper)	Echis ocellatus (Ocellated carpet viper, West African carpet viper)
Snake family		Viperidae
Risk category		Category 1 (Highest Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India

Region of use: Sub-Saharan Africa

WHO prequalification: No

Anti Snake Venom Serum Pan Africa - 10 (Biological E Limited, India)

Alternative name(s): BEAFRIQUE-10, I.H.S

Chemical name: N/A

CAS number: N/A

PCR ID: 1358

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Anti Snake Venom Serum - Pan Africa (10) is a Polyvalent Equine F(ab')2 antivenom also branded as BEAFRIQUE-10. It has an indication for passive immunization against African Snake bite and comes in Liquid & Lyophilized 10 mL Vial. (https://www.fdaghana.gov.gh/img/smpc/Beafrique-10,%2010%20ML,%20Solution%20for%20slow%20Intravenous%20Injection,%20in%20vial%20(Anti%20Snake%20Venom%20Serum).pdf)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Biological E Limited

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Bitis gabonica; Dendroaspis jamesoni; Dendroaspis polylepis; Dendroaspis viridis; Echis leucogaster; Echis ocellatus; Naja haje; Naja melanoleuca; Naja nigricollis
Snake species *(Sources: other)*	**Bitis gabonica (Gaboon viper); Bitis arietans (puff adder); Echis leucogaster (white-bellied carpet viper); Echis ocellatus (West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (forest cobra); Naja nigricollis (black-necked spitting cobra); Dendroaspis polylepis (black mamba); Dendroaspis viridis (western green mamba); Dendroaspis jamesoni (Jameson's mamba)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis gabonica (Gaboon viper); Bitis arietans (puff adder); Echis leucogaster (white-bellied carpet viper); Echis ocellatus (West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (forest cobra); Naja nigricollis (black-necked spitting cobra); Dendroaspis polylepis (black mamba); Dendroaspis viridis (western green mamba); Dendroaspis jamesoni (Jameson's mamba)	Bitis gabonica (Gaboon viper); Bitis arietans (puff adder); Echis leucogaster (white-bellied carpet viper); Echis ocellatus (West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (forest cobra); Naja nigricollis (black-necked spitting cobra); Dendroaspis polylepis (black mamba); Dendroaspis viridis (western green mamba); Dendroaspis jamesoni (Jameson's mamba)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India; Ghana

Region of use: Sub-Saharan Africa

WHO prequalification: No

Antivipmyn Africa (Instituto Bioclon/Laboratorios Silanes, S. A. de C. V., Mexico)

Alternative name(s): Antivip-A

Chemical name: N/A

CAS number: N/A

PCR ID: 1360

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom; sub-Saharan African snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Antivipmyn® Africa antivenom composed of purified lyophilized F(ab')2 fragments of IgG is a polyvalent anti-ophidian antivenom marketed in sub-Saharan Africa. It has been employed in the field in a pragmatic Phase III clinical trial in the Republic of Benin. It is obtained by immunization with the venoms of eleven species of African snakes of the Genera Echis, Bitis, Naja and Dendroaspis. (https://horizon.documentation.ird.fr/exl-doc/pleins_textes/divers17-10/010070599.pdf) Antivipmyn has been assessed in a number of preclinical studies (https://pubmed.ncbi.nlm.nih.gov/32817682/; https://pubmed.ncbi.nlm.nih.gov/27377229/) and anecdotal studies and observations in humans (https://pubmed.ncbi.nlm.nih.gov/29796013/). A 2019 review of the availability of clinical effectiveness evidence for antivenom products commercially available in Sub-Saharan Africa found that Antivipmyn Africa had only been evaluated in observational single-arm studies, with varying results (https://pubmed.ncbi.nlm.nih.gov/31233536/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Laboratorios Silanes; Instituto Bioclon

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/18926842/

Evidence of clinical trials? Yes

Phase IV, (Status: Unknown, March 2008-): *Study to Evaluate the Efficacy of Two Treatment Schemes With Antivipmyn Â® for the Treatment of Snake Bite Envenomation* (CT number: NCT00639951, CT source: https://clinicaltrials.gov/show/NCT00639951)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Bitis gabonica; Dendroaspis polylepis; Dendroaspis viridis; Echis leucogaster; Echis pyramidum; Echis romani; Naja haje; Naja melanoleuca; Naja nigricollis; Naja pallida
Snake species *(Sources: other)*	**B. arietans (puff adder); B. gabonica (Gaboon viper); B. rhinoceros (West African Gaboon viper); D. angusticeps (eastern green mamba); D. jamesoni (Jameson's mamba); D. polylepis (black mamba); D. viridis (western green mamba); E. leucogaster (white-bellied carpet viper); E. ocellatus (West African carpet viper); E. pyramidum (Northeast African carpet viper); N. haje (Egyptian cobra); N. katiensis (Mali cobra); N. melanoleuca, N. nigricollis (Black-necked spitting cobra); N. nivea (Cape cobra)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis nasicornis (butterfly viper); Bitis rhinoceros (West African gaboon viper); Naja annulifera (snouted cobra); Naja katiensis (Mali cobra); Naja mossambica (Mozambique spitting cobra); Naja nivea (Cape cobra); Naja nubiae (Nubian spitting cobra); Haemachatus haemachatus (rinkhals); Dendroaspis angusticeps (eastern green mamba); Causus rhombeatus (rhombic night adder)	B. rhinoceros (West African gaboon viper); C. rhombeatus (rhombic night adder); N. annulifera, N. nivea (Cape cobra); N. katiensis (Mali cobra); N. mossambica (Mozambique spitting cobra); N. nubiae (Nubian spitting cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Mexico

Region of use: Sub-Saharan Africa

WHO prequalification: Yes

ASNA-C (Bharat Serums and Vaccines Limited, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1369

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; sub-Saharan African snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

ASNA-C is a polyvalent F(ab)'2 equine antivenom marketed in sub-Saharan Africa, which neutralises the venoms of Bitis arietans, B. gabonica, B. nasicornis, Dendroaspis angusticeps, D. jamesoni, D. polylepis, Echis carinatus, Naja haje, N. melanoleuca, N.nigricollis and N. nivea. In a good quality post-marketing surveillance study in central Ghana , a region where envenomings are often caused by Echis ocellatus, ASNA-C was associated with a very high mortality rate of 22%, with a mean number of 11.7 vials used per patient. More than half of the 66 treated patients had to be administered repeat antivenom doses. Five cases of anaphylactic shock were reported amongst 66 patients. In a programmatic setting in Nigeria, from a low quality report, ASNA-C was believed to be ineffective in restoring blood coagulopathy, and to cause many cases of allergic reactions - in summary, ASNA-C was found ineffective at neutralising envenomings caused by Echis ocellatus. The rate of severe adverse events appears high. (https://journals.plos.org/plosntds/article/file?id=10.1371/journal.pntd.0007551&type=printable)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Bharat Biotech

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/35324665/

Evidence of clinical trials? Yes

Phase: N/A, (Status: Unknown, -): *N/A* (CT number: N/A, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus caeruleus; Daboia russelii; Echis carinatus; Naja naja
Snake species *(Sources: other)*	**Bitis arietans (Puff adder); Bitis gabonica (Gaboon viper); B. nasicornis (butterfly viper); D. angusticeps (eastern green mamba); D. jamesoni (Jameson's mamba); D. polylepis (black mamba), Echis carinatus (saw-scaled viper); N. haje (Egyptian cobra); N. melanoleuca (forest cobra); N. nigricollis (black-necked spitting cobra); N. nivea (Cape cobra)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis arietans (Puff adder); Bitis gabonica (Gaboon viper); B. nasicornis (butterfly viper); D. angusticeps (eastern green mamba); D. jamesoni (Jameson's mamba); D. polylepis (black mamba), Echis carinatus (saw-scaled viper); N. haje (Egyptian cobra); N. melanoleuca (forest cobra); N. nigricollis (black-necked spitting cobra); N. nivea (Cape cobra)	Bitis arietans (Puff adder); Bitis gabonica (Gaboon viper); B. nasicornis (butterfly viper); D. angusticeps (eastern green mamba); D. jamesoni (Jameson's mamba); D. polylepis (black mamba), Echis carinatus (saw-scaled viper); N. haje (Egyptian cobra); N. melanoleuca (forest cobra); N. nigricollis (black-necked spitting cobra); N. nivea (Cape cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India

Region of use: Sub-Saharan Africa

WHO prequalification: No

Combipack of Snake Venom Antiserum (African- Ten) (Premium Serums and Vaccines Pvt. Ltd., India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 2016

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis Western green mamba); Dendroaspis jamesoni (Jameson's mamba)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

African - Ten snake venom antiserum developed by Premium Serum and Vaccines Limited is a sterile lyophilised preparation contains equine immunoglobulin fragments F(ab')2, derived from the plasma of horses immunised with the venom of the following snake species - Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis Western green mamba); Dendroaspis jamesoni (Jameson's mamba) (https://www.premiumserums.com/product6.html))

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Premium Serums and Vaccines

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis Western green mamba); Dendroaspis jamesoni (Jameson's mamba)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	West Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunisation

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis Western green mamba); Dendroaspis jamesoni (Jameson's mamba)	Bitis arietans (Puff adder); Bitis gabonica (East African Gaboon viper); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis Western green mamba); Dendroaspis jamesoni (Jameson's mamba)
Snake family		Viperidae,Elapidae
Risk category		

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: Sub-Saharan Africa

WHO prequalification: No

EchiTAbG (MicroPharm Ltd, United Kingdom)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1398

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

EchiTAbG is a monospecific antivenom indicated for the treatment of systemic envenoming caused by the bite of the West African saw-scaled or carpet viper, E. ocellatus, as shown by the presence of incoagulable blood or prolonged clotting time or spontaneous systemic bleeding (for example from the gums or nose). Each ampoule contains a minimum of 230 mg of immunoglobulins purified from antisera of sheep immunised with the venom of Echis ocellatus, the West African saw-scaled or carpet viper. (https://www.who.int/docs/default-source/medicines/echitabg-micropharm-1dose-2019-082.pdf)EchiTAbG is officially licensed in Nigeria but is unofficially used in other countries.(https://pubmed.ncbi.nlm.nih.gov/32817682/; https://pubmed.ncbi.nlm.nih.gov/32817674/; https://pubmed.ncbi.nlm.nih.gov/27886134/; https://pubmed.ncbi.nlm.nih.gov/26415904/; https://pubmed.ncbi.nlm.nih.gov/31233536/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: MicroPharm Ltd

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/21049058/

Evidence of clinical trials? Yes

Phase II/Phase III, (Status: Unknown, February 2009-): *Clinical trial of two new anti-snake venoms for the treatment of patients bitten by venomous snakes in Nigeria* (CT number: ISRCTN01257358, CT source: http://isrctn.com/ISRCTN01257358)

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis romani
Snake species *(Sources: other)*	**Echis ocellatus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Nigeria
Regions	West Africa

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of sheep

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Echis coloratus; Echis ocellatus; Echis pyramidum
Snake species *(Sources: Other)*	E. pyramidum leakeyi (Kenyan carpet viper); E. coloratus (painted saw-scaled viper)	Echis ocellatus (West African Carpet viper); Echis pyramidum (East African Carpet viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: United Kingdom; Nigeria

Region of use: Sub-Saharan Africa

WHO prequalification: Yes

EchiTAb-plus-ICP (Instituto Clodomiro Picado, Costa Rica)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1365

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Both

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

EchiTAb™ Plus is produced by the Instituto Clodomiro Picado (ICP), University of Costa Rica, and was developed in collaboration with the EchiTAb study group Nigeria/UK and Liverpool School of Tropical Medicine and University of Oxford. This is an equine trispecific anti-venom raised against the venoms of Nigerian E. ocellatus, Bitis arietans (puff adder) and Naja nigricollis (spitting cobra). These venoms were selected because, from a medical point of view, they are the three most important snake species in Western sub-Saharan Africa. The anti-venom is prepared by caprylic acid precipitation of non-IgG plasma proteins. Preclinical tests using WHO-approved methods showed this antivenom to be as effective or almost as effective against E. ocellatus venom as the original ovine Fab fragment monospecific EchiTAb™. Results of the Randomised Controlled Double-Blind Non-Inferiority Trial in Nigeria were published in 2010 (https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0000767). The final product is presented as a liquid in 10 ml vials with a 3 year expiry period. 30 ml EchiTAb™ Plus is the recommeneded dose in envenomings by E. ocellatus (https://www.echitabplusicp.org/product).(https://pubmed.ncbi.nlm.nih.gov/32817682/; https://pubmed.ncbi.nlm.nih.gov/32817674/; https://pubmed.ncbi.nlm.nih.gov/28847519/; https://pubmed.ncbi.nlm.nih.gov/28478057/; https://pubmed.ncbi.nlm.nih.gov/27886134/; https://pubmed.ncbi.nlm.nih.gov/26415904/; https://pubmed.ncbi.nlm.nih.gov/31233536/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: University of Costa Rica (including the Clodomiro Picado Institute)

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/19699756/

Evidence of clinical trials? Yes

Phase IV, (Status: Unknown, June 2021-): *Optimzing Antivenom Therapy Among Carpet Viper Envenomed Children in Northeastern Nigeria* (CT number: PACTR202106915491232, CT source: https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=15924)

Phase: N/A, (Status: Withdrawn, March 2016-June 2016): *Non-inferiority Trial of Two Snake Antivenoms in CAR (PAVES)* (CT number: NCT02694952, CT source: https://clinicaltrials.gov/show/NCT02694952)

Phase II/Phase III, (Status: Unknown, February 2009-): *Clinical trial of two new anti-snake venoms for the treatment of patients bitten by venomous snakes in Nigeria* (CT number: ISRCTN01257358, CT source: http://isrctn.com/ISRCTN01257358)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Echis romani; Naja nigricollis
Snake species *(Sources: other)*	**Echis ocellatus (West African carpet viper); Bitis arietans (puff adder); Naja nigricollis (Black-necked spitting cobra)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Nigeria
Regions	West Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunisation of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Bitis gabonica; Bitis nasicornis; Bitis rhinoceros; Echis leucogaster; Echis ocellatus; Echis pyramidum; Naja mossambica; Naja pallida
Snake species *(Sources: Other)*	Echis ocellatus; Echis leucogaster; Echis pyramidum; Echis pyramidum leakey; Bitis arietans; Bitis gabonica; Bitis rhinoceros; Bitis nasicornis; Naja ashei; Naja nigricollis; Naja katiensis; Naja mossambica; Naja pallida; Naja annulifera; Naja nigricinta nigricinta; Dendroaspis polylepis	Echis ocellatus; Echis leucogaster; Echis pyramidum; Echis pyramidum leakey; Bitis arietans; Bitis gabonica; Bitis rhinoceros; Bitis nasicornis; Naja ashei; Naja nigricollis; Naja katiensis; Naja mossambica; Naja pallida; Naja annulifera; Naja nigricinta nigricinta; Dendroaspis polylepis
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Costa Rica; Nigeria; Burkina Faso

Region of use: Sub-Saharan Africa

WHO prequalification: Yes

FAV-Afrique (Sanofi Pasteur, MicroPharm)

Alternative name(s): FAV-Africa, FAV-A

Chemical name: N/A

CAS number: N/A

PCR ID: 1437

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: B. arietans, B. gabonica, D. jamesoni, D. polylepis, D. viridis, E. leucogaster, E. ocellatus, N. haje, N. melanoleuca N. nigricollis

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2°C - 8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

FAV-Afrique is no longer in production and research has been conducted on the comparative efficacy of recombinant antivenoms to this polyvalent antivenom. Sanofi ceased its manufacture in early 2016 after a more than a decade of commercial disincentives. A recent market failure affected snakebite-treatment capability in those state, private (mostly city-based) and charity hospitals that could afford this relatively expensive antivenom. It was found to have been evaluated only in observational single-arm studies, with varying results. MicroPharm, has announced its intention to re-launch the product. The one linked clinical trial entry was never approved by the study sponsor and it was ultimately withdrawn. MicroPharm Limited is pleased to announce the acquisition of Sanofi Pasteur's antivenom equine immunoglobulin product range comprising Viperfav®, Bothrofav® Scorpifav®, Fav-Afrique® and Favirept®. The transaction comprises the transfer of the intangible and some tangible assets to MicroPharm. Over the next three years MicroPharm and Sanofi Pasteur will work together to transfer the manufacture of Viperfav, Bothrofav and Scorpifav to MicroPharm's manufacturing facilities in West Wales. MicroPharm will seek to re-launch Fav-Afrique and Favirept to the African and Middle East markets where there is an unmet need for safe and effective antivenoms tailored to these regions (https://micropharm.co.uk/news/2018/1/acquisition_of_sanofi_pasteurs_equine_antivenom_immunoglobulin_products)(https://pubmed.ncbi.nlm.nih.gov/32766215/; https://pubmed.ncbi.nlm.nih.gov/29369078/; https://pubmed.ncbi.nlm.nih.gov/29045429/; https://pubmed.ncbi.nlm.nih.gov/27886134/; https://pubmed.ncbi.nlm.nih.gov/26415904/; https://pubmed.ncbi.nlm.nih.gov/31233536/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Sanofi Pasteur; MicroPharm Ltd

Preclinical results status: Yes

Evidence of clinical trials? Yes

Phase: N/A, (Status: Withdrawn, March 2016-June 2016): *Non-inferiority Trial of Two Snake Antivenoms in CAR (PAVES)* (CT number: NCT02694952, CT source: https://clinicaltrials.gov/show/NCT02694952)

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Bitis arietans (puff adder); Bitis gabonica (Gaboon viper); Dendroaspis jamesoni (Jameson's mamba); Dendroaspis polylepis (black mamba); Dendroaspis viridis (green mamba); Echis leucogaster (white-bellied carpet viper); Echis ocellatus (West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (forest cobra); Naja nigricollis (black-necked spitting cobra)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent immunization of horses to obtain monospecific antisera, then combined to form polyvalent antivenom

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis arietans (puff adder); Bitis gabonica (Gaboon viper); Dendroaspis jamesoni (Jameson's mamba); Dendroaspis polylepis (black mamba); Dendroaspis viridis (green mamba); Echis leucogaster (white-bellied carpet viper); Echis ocellatus (West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (forest cobra); Naja nigricollis (black-necked spitting cobra)	Bitis arietans (puff adder); Bitis gabonica (Gaboon viper); Dendroaspis jamesoni (Jameson's mamba); Dendroaspis polylepis (black mamba); Dendroaspis viridis (green mamba); Echis leucogaster (white-bellied carpet viper); Echis ocellatus (West African carpet viper); Naja haje (Egyptian cobra); Naja melanoleuca (forest cobra); Naja nigricollis (black-necked spitting cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Discontinued

Approval status: Approved

Approving authority: NRA

Region of use: Sub-Saharan Africa

WHO prequalification: No

Inoserp PAN-AFRICA (INOSAN BIOPHARMA S. A., Spain)

Alternative name(s): Inoserp-P

Chemical name: N/A

CAS number: N/A

PCR ID: 1354

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; sub-Saharan African snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 8°C - 30°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Inoserp PAN-AFRICA is a polyvalent F(ab')2 immunoglobulin fragment (equine) snake antivenom, neutralizing with high specificity the venoms of sub-Saharan Africa species. Inoserp PANAFRICA is indicated for the treatment of envenoming caused by the bite of the following species: VIPERIDAE: Echis ocellatus, Echis leucogaster, Echis pyramidum, Bitis arietans, Bitis rhinoceros, Bitis nasicornis, Bitis gabonica; and ELAPIDAE: Dendroaspis polylepis, Dendroaspis viridis, Dendroaspis angusticeps, Dendroaspis jamesoni, Naja nigricollis, Naja melanoleuca, Naja haje, Naja pallida, Naja nubiae, Naja katiensis and Naja senegalensis. MSF Epicenter ran a Phase IV clinical trial in 14 healthcare centers across 6 of the 10 regions of Cameroon which yielded positive results for safety and tolerance (https://pubmed.ncbi.nlm.nih.gov/31233536/; https://epicentre.msf.org/sites/default/files/2021-07/11_Abstracts_Epicentre_JS_2021_Karl.pdf)(https://inosanbiopharma.com/assets/Abbreviated_Prescribing_Information-ISPA_250-1411-2019.pdf; https://pubmed.ncbi.nlm.nih.gov/32817682/; https://pubmed.ncbi.nlm.nih.gov/29045429/; https://pubmed.ncbi.nlm.nih.gov/27886134/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: INOSAN Biopharma SA

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/29045429/https://pubmed.ncbi.nlm.nih.gov/26415904/

Evidence of clinical trials? Yes

Phase: N/A, (Status: Completed, October 2019-September 2021): *Evaluation of Anti-venoms Serum in Africa* (CT number: NCT03326492, CT source: https://clinicaltrials.gov/show/NCT03326492)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Bitis nasicornis; Dendroaspis angusticeps; Dendroaspis polylepis; Dendroaspis viridis; Echis leucogaster; Echis ocellatus; Naja katiensis; Naja melanoleuca; Naja nigricollis; Naja pallida
Snake species *(Sources: other)*	**Naja nigricollis (black-necked spitting cobra); Dendroaspis polylepis (black mamba); Echis ocellatus (West African carpet viper); Bitis arietans (puff adder)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Bitis gabonica; Bitis rhinoceros; Dendroaspis jamesoni; Echis pyramidum; Naja nubiae; Naja senegalensis
Snake species *(Sources: Other)*	Echis ocellatus (West African carpet viper); Echis leucogaster (white-bellied carpet viper); Echis pyramidum (Northeast African carpet viper); Bitis arietans (puff adder); Bitis rhinoceros (West African Gaboon viper); Bitis nasicornis (butterfly viper); Bitis gabonica (Gaboon viper); Dendroaspis polylepis (black mamba); Dendroaspis viridis (western green mamba); Dendroaspis angusticeps (eastern green mamba); Dendroaspis jamesoni (Jameson's mamba); Naja nigricollis (black-necked spitting cobra); Naja melanoleuca (forest cobra); Naja haje (Egyptian cobra); Naja pallida (red spitting cobra); Naja nubiae (Nubian spitting cobra); Naja katiensis (Mali cobra); Naja senegalensis (Senegalese cobra)	Echis ocellatus (West African carpet viper); Echis leucogaster (white-bellied carpet viper); Echis pyramidum (Northeast African carpet viper); Bitis arietans (puff adder); Bitis rhinoceros (West African Gaboon viper); Bitis nasicornis (butterfly viper); Bitis gabonica (Gaboon viper); Dendroaspis polylepis (black mamba); Dendroaspis viridis (western green mamba); Dendroaspis angusticeps (eastern green mamba); Dendroaspis jamesoni (Jameson's mamba); Naja nigricollis (black-necked spitting cobra); Naja melanoleuca (forest cobra); Naja haje (Egyptian cobra); Naja pallida (red spitting cobra); Naja nubiae (Nubian spitting cobra); Naja katiensis (Mali cobra); Naja senegalensis (Senegalese cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Mexico; Benin; Burkina Faso; Gabon; Ghana; Guinea; Cote D`Ivoire (Ivory Coast); Kenya; Mali; Senegal; Tanzania; Togo; Uganda; Cameroon

Region of use: Sub-Saharan Africa

WHO prequalification: No

SAIMR Boomslang antivenom (South African Vaccine Producers, South Africa)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1413

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Dispholidus typus (Boomslang)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The South African Vaccine Producers manufacture the monovalent antivenom SAIMR Boomslang which is indicated for the treatment of local and systemic envenomation following bites from Dispholidus typus (Boomslang) (http://www.savp.co.za/?page=products&id=11). It is comprised of F(ab)2 immunoglobulin fragments derived from the plasma of horses immunized with the snake's venom (https://pubmed.ncbi.nlm.nih.gov/31233536/). There is sparse preclinical and clinical data about this candidate's efficacy, however, a preclinical study has established its high degree of paraspecific neutralisation by inhibiting the procoagulant effects of the venom of 10 different vipers (https://pubmed.ncbi.nlm.nih.gov/30271920/). These findings were attributed to the specific inhibition of SVMP toxins within the venom of these snake species, by SAIMR Boomslang (https://pubmed.ncbi.nlm.nih.gov/30271920/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: South African National Health Laboratory Service (NHLS) (including NICD and SAVP)

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/30271920/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Dispholidus typus
Snake species *(Sources: other)*	**Dispholidus typus (Boomslang)**
Snake family	**Colubridae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	South Africa
Regions	Southern Africa

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Dispholidus typus (Boomslang)	Dispholidus typus (Boomslang)
Snake family		Colubridae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: SVMPs

Syndromic profiles: Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: South Africa

Region of use: Sub-Saharan Africa

WHO prequalification: No

SAIMR Echis antivenom (South African Vaccine Producers, South Africa)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1416

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Echis carinatus (Saw-scaled viper), Echis ocellatus (Ocellated carpet viper, West African carpet viper), Echis pyramidum (East African carpet viper, Egyptian saw scaled viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The SAIMR Echis antivenom is a polyvalent equine F(ab)'2 antivenom manufactured by the South African Vaccine Producers (http://www.savp.co.za/?page=products&id=11) and marketed in sub-Saharan Africa and derived by immunizing horses with the venom of three Echis species - Echis carinatus (Saw-scaled viper), Echis ocellatus (Ocellated carpet viper, West African carpet viper), Echis pyramidum (East African carpet viper, Egyptian saw scaled viper) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5646754/). It is effective for the neutralisation of hemorrhagic and procoagulant effects of systemic Echis envenomation (https://pubmed.ncbi.nlm.nih.gov/28847519/).Its efficacy against Echis ocellatus has been investigated and proven by several preclinical studies (https://pubmed.ncbi.nlm.nih.gov/19874841/) (https://pubmed.ncbi.nlm.nih.gov/20412814/), as well as in a clinical trial (https://pubmed.ncbi.nlm.nih.gov/4154124/), observational cohort study (https://pubmed.ncbi.nlm.nih.gov/1265825/) and in anecdotal case reports (https://pubmed.ncbi.nlm.nih.gov/866568/).

Other indications investigated: n/a

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: South African National Health Laboratory Service (NHLS) (including NICD and SAVP)

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/19874841/https://pubmed.ncbi.nlm.nih.gov/20412814/

Evidence of clinical trials? Yes

Phase: N/A, (Status: Results submitted, -): *Bites by the saw-scaled or carpet viper (Echis carinatus): trial of two specific antivenoms* (CT number: N/A, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis ocellatus; Echis pyramidum
Snake species *(Sources: other)*	**Echis carinatus (Saw-scaled viper), Echis ocellatus (Ocellated carpet viper, West African carpet viper), Echis pyramidum (East African carpet viper, Egyptian saw scaled viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	West Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Echis carinatus (Saw-scaled viper), Echis ocellatus (Ocellated carpet viper, West African carpet viper), Echis pyramidum (East African carpet viper, Egyptian saw scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Cerastes sp	Echis carinatus (Saw-scaled viper), Echis ocellatus (Ocellated carpet viper, West African carpet viper), Echis pyramidum (East African carpet viper, Egyptian saw scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Cerastes sp
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: South Africa

Region of use: Sub-Saharan Africa

WHO prequalification: No

SAIMR Polyvalent Snake antivenom (South African Vaccine Producers, South Africa)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1320

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The SAIMR polyvalent antivenom, manufactured by the South African Vaccine Producers (SAVP), is a liquid Equine F(ab')2 antivenom. SAIMR-Poly is one of the most clinically-trusted antivenoms in sub-Saharan Africa, but there is little evidence of the effectiveness. A trial was run in 1974 with limited sample. (https://www.jstor.org/stable/20471139?seq=2)An analysis of preclinical efficacy testing of antivenoms for sub-Saharan Africa found inadequate independent scrutiny and poor-quality reporting are barriers to improving snakebite treatment and management. The paper found that SAIMR Polyvalent demonstrated consistently more-efficacious anti-elapid (and more anti-viper-like) ED50s, compared to other polyvalent antivenoms. Notably, SAIMR Polyvalent, an antivenom which is not indicated for the treatment of E. ocellatus, as this venom is not including in the immunising mixture, was found to have preclinical efficacy against E. ocellatus envenoming in the single study in which it was tested, although the resulting ED50 value was relatively lower compared to other products (https://pubmed.ncbi.nlm.nih.gov/32817682/)SAIMR polyvalent has additionally been preclinically tested against Night adders (Causus species within the Viperidae family), specifically C. rhombeatus and C. lichtensteinii. The study found that SAIMR polyvalent that C. lichtensteinii venom was unaffected at the dose tested while C. rhombeatus was moderately but significantly neutralized (https://pubmed.ncbi.nlm.nih.gov/29758383/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: South African National Health Laboratory Service (NHLS) (including NICD and SAVP)

Preclinical results status: Available

Preclinical sources: https://www.biorxiv.org/content/10.1101/2022.05.16.492230v2.full

Evidence of clinical trials? Yes

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Bitis gabonica; Dendroaspis angusticeps; Dendroaspis jamesoni; Dendroaspis polylepis; Hemachatus haemachatus; Naja annulifera; Naja melanoleuca; Naja mossambica; Naja nivea
Snake species *(Sources: other)*	**Bitis arietans (Puff Adder); Bitis gabonica (Gaboon Adder/Viper); Hemachatus hemachatus (Rinkhals); Dendroaspis angusticeps (Green Mamba); Dendroaspis jamesoni (Jameson's Mamba); Dendroaspis polylepis (Black Mamba) Naja nivea (Cape Cobra); Naja melanoleuca (Forest Cobra); Naja annulifera (Egyptian Cobra); Naja mossambica (Black-necked, or Spitting Cobra)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	South Africa
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Bitis parviocula
Snake species *(Sources: Other)*	Bitis arietans (Puff Adder); Bitis gabonica (Gaboon Adder/Viper); Hemachatus hemachatus (Rinkhals); Dendroaspis angusticeps (Green Mamba); Dendroaspis jamesoni (Jameson's Mamba); Dendroaspis polylepis (Black Mamba) Naja nivea (Cape Cobra); Naja melanoleuca (Forest Cobra); Naja annulifera (Egyptian Cobra); Naja mossambica (Black-necked, or Spitting Cobra)	Bitis arietans (Puff Adder); Bitis gabonica (Gaboon Adder/Viper); Hemachatus hemachatus (Rinkhals); Dendroaspis angusticeps (Green Mamba); Dendroaspis jamesoni (Jameson's Mamba); Dendroaspis polylepis (Black Mamba) Naja nivea (Cape Cobra); Naja melanoleuca (Forest Cobra); Naja annulifera (Egyptian Cobra); Naja mossambica (Black-necked, or Spitting Cobra)
Snake family		Viperidae,Elapidae
Risk category		Unknown

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: South Africa

Region of use: Sub-Saharan Africa

WHO prequalification: Yes

Snake Venom Antiserum - Central Africa (Premium Serums and Vaccines Pvt. Ltd., India)

Alternative name(s): Combipack of snake venom antiserum (Central Africa)

Chemical name: N/A

CAS number: N/A

PCR ID: 1940

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Bitis rhinoceros (West African Gaboon viper); Echis carinatus (Saw-scaled viper); Dendroaspis polylepis (Black mamba); Daboia russelli (Indian Russell's viper, Russell's viper, South Asian Russell's viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Snake Venom Antiserum is a polyvalent antivenin developed by Premium Serum and Vaccines Ltd, India. It is comprised of F(ab)'2 immunoglobulins derived from the plasma of horses immunised with the venom of four important Indian snakes - Bitis rhinoceros (West African Gaboon viper); Echis carinatus (Saw-scaled viper); Dendroaspis polylepis (Black mamba); Daboia russelli (Indian Russell's viper, Russell's viper, South Asian Russell's viper) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7462309/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Premium Serums and Vaccines

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Bitis rhinoceros (West African Gaboon Viper), Echis carinatus (Saw-scaled Viper), Daboia russelii (Russel's Viper) and Dendroaspis polylepis (Black Mamba)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis rhinoceros (West African Gaboon viper); Echis carinatus (Saw-scaled viper); Dendroaspis polylepis (Black mamba); Daboia russelli (Indian Russell's viper, Russell's viper, South Asian Russell's viper)	Bitis rhinoceros (West African Gaboon viper); Echis carinatus (Saw-scaled viper); Dendroaspis polylepis (Black mamba); Daboia russelli (Indian Russell's viper, Russell's viper, South Asian Russell's viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: Sub-Saharan Africa

WHO prequalification: No

Snake venom antiserum - Pan Africa (Premium Serums and Vaccines Pvt. Ltd., India)

Alternative name(s): Combipack of snake venom antiserum (PAN-AF)

Chemical name: N/A

CAS number: N/A

PCR ID: 1355

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom; sub-Saharan African snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Traditional antivenoms are derived from the plasma/serum of mammals – usually horses – hyperimmunized with selected snake venom(s). The plasma, which contains snake venom-specific immunoglobulins, is then isolated and purified, with immunoglobulins either left intact as whole Ig (IgG) format, or cleaved into F(ab')2 or F(ab) antibody fragments. F(ab')2 fragment antibodies are generated by pepsin digestion of whole IgG antibodies to remove most of the Fc region, leaving some of the hinge region. F(ab')2 fragments have two antigen-binding F(ab) portions linked together by disulfide bonds, so are divalent with a molecular weight of about 110 kDa. (https://www.abcam.com/secondary-antibodies/advantages-of-immunoglobulin-fab-and-fab2-fragments).Most antivenoms are available in liquid or freeze-dried format (to improve stability), and administered intravenously. Although traditional equine plasma derived antivenoms are expensive to develop, labour intensive, and highly immunogenic, often causing severe side effects such as serum sickness or anaphylactic shock, they are nonetheless relatively effective, and currently the only approved therapeutics for snakebite envenoming.(https://pubmed.ncbi.nlm.nih.gov/29045429/; https://pubmed.ncbi.nlm.nih.gov/27886134/; https://pubmed.ncbi.nlm.nih.gov/27377229/; https://pubmed.ncbi.nlm.nih.gov/27377229/; https://pubmed.ncbi.nlm.nih.gov/31233536/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Premium Serums and Vaccines

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Bitis gabonica; Bitis nasicornis; Bitis rhinoceros; Dendroaspis angusticeps; Dendroaspis jamesoni; Dendroaspis polylepis; Dendroaspis viridis; Echis carinatus; Echis leucogaster; Echis ocellatus; Echis romani; Naja haje; Naja melanoleuca; Naja nigricollis
Snake species *(Sources: other)*	**Bitis arietans; Bitis gabonica; Bitis nasicornis; Bitis rhinoceros; Echis leucogaster; Echis ocellatus; Echis carinatus; Naja haje; Naja melanoleuca; Naja nigricollis; Dendroaspis polylepis; Dendroaspis viridis; Dendroaspis jamesoni; Dendroaspis angusticeps**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bitis arietans; Bitis gabonica; Bitis nasicornis; Bitis rhinoceros; Echis leucogaster; Echis ocellatus; Echis carinatus; Naja haje; Naja melanoleuca; Naja nigricollis; Dendroaspis polylepis; Dendroaspis viridis; Dendroaspis jamesoni; Dendroaspis angusticeps	Bitis arietans; Bitis gabonica; Bitis nasicornis; Bitis rhinoceros; Echis leucogaster; Echis ocellatus; Echis carinatus; Naja haje; Naja melanoleuca; Naja nigricollis; Dendroaspis polylepis; Dendroaspis viridis; Dendroaspis jamesoni; Dendroaspis angusticeps
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India

Region of use: Sub-Saharan Africa

WHO prequalification: Yes

Snake Venom Antiserum African - 10 (VINS-A) (VINS Bioproducts Ltd, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1968

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis (Western green mamba); Dendroaspis jamesoni (Jameson's mamba); Bitis gabonica (East African Gaboon viper); Bitis arietans (Puff adder); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Snake Venom Antiserum (African) is a sterile preparation contains equine immunoglobulin fragments F(ab')2. Freeze dried powder is reconstituted in 10 ml of sterile water for Injection supplied along with the vial. Each ml has power of specifically neutralizing the venoms of following species of snakes - Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis (Western green mamba); Dendroaspis jamesoni (Jameson's mamba); Bitis gabonica (East African Gaboon viper); Bitis arietans (Puff adder); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper) (https://vinsbio.in/african-10/).It has also been found to have paraspecificity against - Naja pallida (Red spitting cobra); Echis Pyramidum (East African carpet viper, Egyptian saw scaled viper); Bitis Rhinoceros (West African Gaboon viper); Bitis Nacicornis; Dendroaspis Angusticeps (Eastern green mamba); Naja Mozambique; Naja Ashei (Ashe's spitting cobra) (https://vinsbio.in/african-10/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VINS Bioproducts

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Bitis gabonica; Dendroaspis jamesoni; Dendroaspis polylepis; Dendroaspis viridis; Echis leucogaster; Echis ocellatus; Naja haje; Naja melanoleuca; Naja nigricollis
Snake species *(Sources: other)*	**Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis (Western green mamba); Dendroaspis jamesoni (Jameson's mamba); Bitis gabonica (East African Gaboon viper); Bitis arietans (Puff adder); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	West Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunisation

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis (Western green mamba); Dendroaspis jamesoni (Jameson's mamba); Bitis gabonica (East African Gaboon viper); Bitis arietans (Puff adder); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper); Naja pallida (Red spitting cobra); Echis Pyramidum (East African carpet viper, Egyptian saw scaled viper); Bitis Rhinoceros (West African Gaboon viper); Bitis Nacicornis; Dendroaspis Angusticeps (Eastern green mamba); Naja Mozambique; Naja Ashei (Ashe's spitting cobra)	Naja melanoleuca (Black & white cobra, Forest cobra); Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Dendroaspis viridis (Western green mamba); Dendroaspis jamesoni (Jameson's mamba); Bitis gabonica (East African Gaboon viper); Bitis arietans (Puff adder); Echis leucogaster (Roman's saw scaled viper, White-bellied carpet viper); Echis ocellatus (Ocellated carpet viper, West African carpet viper); Naja pallida (Red spitting cobra); Echis Pyramidum (East African carpet viper, Egyptian saw scaled viper); Bitis Rhinoceros (West African Gaboon viper); Bitis Nacicornis; Dendroaspis Angusticeps (Eastern green mamba); Naja Mozambique; Naja Ashei (Ashe's spitting cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Kenya; Cote D`Ivoire (Ivory Coast); Nigeria; Ghana; Zambia

Region of use: Sub-Saharan Africa

WHO prequalification: No

Snake Venom Antiserum Echis Ocellatus - Echiven (VINS Bioproducts Ltd, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1415

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Echis Ocellatus (Ocellated carpet viper, West African carpet viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The snake venom antiserum Echis cellatus is a sterile preparation containing equine F(ab')2 immunoglobulin fragments derived from the blood of horses immunized against the venom of the carpet viper - Echis ocellatus (https://vinsbio.in/echiven/). While there is a shortage of preclinical evidence of its efficacy, the available evidence suggests that this product actually lacks preclinical efficacy against the venom of Echis ocellatus (https://pubmed.ncbi.nlm.nih.gov/27377229/). There is also no publicly available clinical evidence of its efficacy (https://pubmed.ncbi.nlm.nih.gov/31233536/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VINS Bioproducts

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/27377229/https://pubmed.ncbi.nlm.nih.gov/27377229/

Evidence of clinical trials? No

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Echis Ocellatus (Ocellated carpet viper, West African carpet viper)**
Snake family	**Viperidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	
Regions	West Africa

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Echis Ocellatus (Ocellated carpet viper, West African carpet viper)	Echis Ocellatus (Ocellated carpet viper, West African carpet viper)
Snake family		Viperidae
Risk category		Category 1 (Highest Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: Sub-Saharan Africa

WHO prequalification: No

Snake Venom Antiserum Echiven Plus (VINS Bioproducts Ltd, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 2017

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Bitis arietans (Puff adder); Echis ocellatus (Ocellated carpet viper, West African carpet viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Traditional antivenoms are derived from the plasma/serum of mammals – usually horses – hyperimmunized with selected snake venom(s). The plasma, which contains snake venom-specific immunoglobulins, is then isolated and purified, with immunoglobulins either left intact as whole Ig (IgG) format, or cleaved into F(ab')2 or F(ab) antibody fragments.F(ab')2 fragment antibodies are generated by pepsin digestion of whole IgG antibodies to remove most of the Fc region, leaving some of the hinge region. F(ab')2 fragments have two antigen-binding F(ab) portions linked together by disulfide bonds, so are divalent with a molecular weight of about 110 kDa. (https://www.abcam.com/secondary-antibodies/advantages-of-immunoglobulin-fab-and-fab2-fragments)Most antivenoms are available in liquid or freeze-dried format (to improve stability), and administered intravenously. Although traditional equine plasma derived antivenoms are expensive to develop, labour intensive, and highly immunogenic, often causing severe side effects such as serum sickness or anaphylactic shock, they are nonetheless relatively effective, and currently the only approved therapeutics for snakebite envenoming.ECHIVEN PLUS is a sterile preparation contains equine immunoglobulin fragments F(ab')2 derived from the plasma of horses immunised with the venom of the following snake species - Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Bitis arietans (Puff adder); Echis ocellatus (Ocellated carpet viper, West African carpet viper) (https://vinsbio.in/echiven-plus/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VINS Bioproducts

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis ocellatus
Snake species *(Sources: other)*	**Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Bitis arietans (Puff adder); Echis ocellatus (Ocellated carpet viper, West African carpet viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	
Regions	Southern Africa

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunisation

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Bitis arietans (Puff adder); Echis ocellatus (Ocellated carpet viper, West African carpet viper)	Naja nigricollis (Black-necked spitting cobra); Naja haje (Egyptian cobra); Dendroaspis polylepis (Black mamba); Bitis arietans (Puff adder); Echis ocellatus (Ocellated carpet viper, West African carpet viper)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Jordan

Region of use: Sub-Saharan Africa

WHO prequalification: No

Middle East

Bivalent Naja/Walterinnesia Snake AV - Equine (National Antivenom & Vaccine Production Center, Saudi Arabia)

Alternative name(s): Trade name: Cobra Antivenom (Equine) AMP

Chemical name: N/A

CAS number: N/A

PCR ID: 1352

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Naja arabica (Arabian cobra); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja naja (Indian cobra, Spectacled cobra); Naja nigricollis (Black-necked spitting cobra); Naja nivea (Cape cobra); Walterinnesia aegyptia (Desert cobra, Peten); Walterinnesia morgani (Morgan's desert cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Developed by the Saudi Arabian National Antivenom & Vaccine Production Center (NAVPC) (https://antivenom-center.com/?page_id=77), the Bivalent Naja/Walterinnesia Snake Antivenom was raised from the blood of horses immunised with the venoms of some of Saudi Arabia's most deadly snakes, including Naja arabica (Arabian cobra); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja naja (Indian cobra, Spectacled cobra); Naja nigricollis (Black-necked spitting cobra); Naja nivea (Cape cobra); Walterinnesia aegyptia (Desert cobra, Peten); Walterinnesia morgani (Morgan's desert cobra) (http://www.antivenoms.toxinfo.med.tum.de/productinfo/BIVALENT_NAJA_WALTERINNESIA_SNAKE_ANTIVENOM.html)Saudi Food and Drug Authority (SFDA) registration number: 3-308-98 - https://sfda.gov.sa/en/node/78034

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: National Antivenom and Vaccine Production Centre (NAVPC), Saudi Arabia

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Naja arabica; Naja haje; Walterinnesia aegyptia
Snake species *(Sources: other)*	**Naja arabica (Arabian cobra); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja naja (Indian cobra, Spectacled cobra); Naja nigricollis (Black-necked spitting cobra); Naja nivea (Cape cobra); Walterinnesia aegyptia (Desert cobra, Peten); Walterinnesia morgani (Morgan's desert cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Saudi Arabia
Regions	Middle East

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Walterinnesia morgani
Snake species *(Sources: Other)*	Naja arabica (Arabian cobra); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja naja (Indian cobra, Spectacled cobra); Naja nigricollis (Black-necked spitting cobra); Naja nivea (Cape cobra); Walterinnesia aegyptia (Desert cobra, Peten); Walterinnesia morgani (Morgan's desert cobra)	Manufacturer label claims paraspecificity against Walterinnesia morganiNaja arabica (Arabian cobra); Naja haje (Egyptian cobra); Naja melanoleuca (Black & white cobra, Forest cobra); Naja naja (Indian cobra, Spectacled cobra); Naja nigricollis (Black-necked spitting cobra); Naja nivea (Cape cobra); Walterinnesia aegyptia (Desert cobra, Peten); Walterinnesia morgani (Morgan's desert cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Saudi Arabia

Region of use: Middle East

WHO prequalification: No

Echis Coloratus Equine Antiserum (Kamada Limited, Israel)

Alternative name(s): Snake bite antiserum

Chemical name: N/A

CAS number: N/A

PCR ID: 1414

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Echis coloratus (Burton's carpet viper, Palestine saw scaled viper)

Route of administration: Intravenous

Ig format: Unknown

Ig final product type/preparation: Unknown

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Kamada Equine Antiserum is a monospecific antivenom indicated for treating systemic envenomation following bites from Echis coloratus (Burton's carpet viper, Palestine saw scaled viper) (https://www.tandfonline.com/doi/abs/10.1080/15563650.2019.1598646). It has been shown to be effective in treating procoagulant effects of systemic Echis coloratus envenoming in an anecdotal clinical reports (https://www.tandfonline.com/doi/abs/10.1080/15563650.2019.1598646) and (https://www.acmt.net/_Library/2019_Israeli_Conference/thrombotic_-_Lurie.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Kamada Ltd

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis coloratus
Snake species *(Sources: other)*	**Echis coloratus (Burton's carpet viper, Palestine saw scaled viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Israel
Regions	Middle East

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Echis coloratus (Burton's carpet viper, Palestine saw scaled viper)	Echis coloratus (Burton's carpet viper, Palestine saw scaled viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Israel

Region of use: Middle East

WHO prequalification: No

Hexavalent snake venom immunoglobulin (Razi Vaccine & Serum Research Institute, Iran)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1337

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Echis carinatus (Saw-scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montiviperaraddei albicornuta (Iranian mountain viper); Agkistrodon halys (Caucasian pitviper); Pseudocerastes persicus (Persian horned viper, Shfifon); Naja oxiana (Central Asian cobra, Transcaspian cobra); Macrovipera razii

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Razi™ polyvalent (hexavalent) antivenin (https://www.rvsri.ac.ir/Tolid/Portal/home/?website/238297/238373/238936/) is a commercially available treatment for snakebite in Iran and is approved by Iranian Ministry of Health and Medical Education. It is a F(ab')2 antivenom product which is derived from equine hyperimmune serum and capable of neutralizing the venom of 6 most common snakes in Iran including 5 viper species (Echis carinatus sochureki, Vipera lebetina obtusa, Vipera albicornuta, Agkistrodon halys, Pseudocerastes persicus) and an elapidae species (Naja naja oxiana). This product has been efficiently used in treatment of snakebite with limited adverse effects. The manufacturer has recommended administering 1-2 vial attack doses until stabilizing the patient or reversal of venom effects (https://apjmt.mums.ac.ir/article_42_48422fc8cdec52c1accd79d21cad893d.pdf). It is being investigated in a Phase III efficacy trial with a new polyvalent antivenom developed by Padra Serum Alborz (https://www.irct.ir/trial/41983). Its efficacy against Echis carinatus was shown in a preclinical study (https://pubmed.ncbi.nlm.nih.gov/29201102/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Razi Vaccine & Serum Research Institute, Iran

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/29201102/

Evidence of clinical trials? Yes

Phase III, (Status: Unknown, February 2020-): *Phase 3, multi-center clinical trial for evaluation of two types of snake anti-venom* (CT number: IRCT20180515039672N2, CT source: http://en.irct.ir/trial/41983)

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis carinatus; Gloydius halys caucasicus; Macrovipera lebetina; Montivipera raddei; Naja oxiana; Pseudocerastes persicus
Snake species *(Sources: other)*	**Echis carinatus (Saw-scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montiviperaraddei albicornuta (Iranian mountain viper); Agkistrodon halys (Halys pitviper); Pseudocerastes persicus (Persian horned viper, Shfifon); Naja oxiana (Central Asian cobra, Transcaspian cobra); Macrovipera razii**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Iran
Regions	Middle East

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Echis carinatus (Saw-scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montiviperaraddei albicornuta (Iranian mountain viper); Agkistrodon halys (Halys pitviper); Pseudocerastes persicus (Persian horned viper, Shfifon); Naja oxiana (Central Asian cobra, Transcaspian cobra); Macrovipera razii	Echis carinatus (Saw-scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montiviperaraddei albicornuta (Iranian mountain viper); Agkistrodon halys (Halys pitviper); Pseudocerastes persicus (Persian horned viper, Shfifon); Naja oxiana (Central Asian cobra, Transcaspian cobra); Macrovipera razii
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Iran

Region of use: Middle East

WHO prequalification: No

Pentavalent snake antivenom immunoglobulin (Razi Vaccine & Serum Research Institute, Iran)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1338

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Echis carinatus (Saw-scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei albicornuta (Iranian mountain viper); Agkistrodon halys (Caucasian pitviper); Pseudocerastes persicus (Persian horned viper, Shfifon)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Razi™ polyvalent (pentavalent) antivenin (https://www.rvsri.ac.ir/Tolid/Portal/home/?website/238297/238373/238934/) is a commercially available treatment for snakebite in Iran and is approved by Iranian Ministry of Health and Medical Education. It is a F(ab')2 antivenom product which is derived from equine hyperimmune serum and capable of neutralizing the venom of 5 most common snakes in Iran including 5 viper species (Echis carinatus sochureki, Vipera lebetina obtusa, Vipera albicornuta, Agkistrodon halys, Pseudocerastes persicus). This product has been efficiently used in treatment of snakebite with limited adverse effects. The active ingredients of this antidote include F (ab ') 2 snake venom immunoglobulins, each millilitre of which has the ability to Of the 50 LD-50 from the venom of each of these snakes based on its lethal properties in preclinical mice studies. It is being investigated in a Phase III efficacy trial with a new polyvalent antivenom developed by Padra Serum Alborz (https://www.irct.ir/trial/41983). Its efficacy against Echis carinatus venom was shown in a preclinical study (https://pubmed.ncbi.nlm.nih.gov/29201102/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Razi Vaccine & Serum Research Institute, Iran

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase III, (Status: Active, February 2020-): *Phase 3, multi-center, randomized, two-arm, parallel, double blinded, active controlled for non-inferiority evaluation of efficacy and safety of snake anti-venom produced by Padra Serum Alborz in comparison with snake anti-venom produced by Razi Vaccine and Serum Research Institute in snakebite victims* (CT number: IRCT20180515039672N2, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis carinatus; Gloydius halys caucasicus; Macrovipera lebetina; Montivipera raddei; Pseudocerastes persicus
Snake species *(Sources: other)*	**Echis carinatus (Saw-scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei albicornuta (Iranian mountain viper); Agkistrodon halys (Caucasian pitviper); Pseudocerastes persicus (Persian horned viper, Shfifon)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Iran
Regions	Middle East

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Echis carinatus (Saw-scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei albicornuta (Iranian mountain viper); Agkistrodon halys (Caucasian pitviper); Pseudocerastes persicus (Persian horned viper, Shfifon)	Echis carinatus (Saw-scaled viper); Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei albicornuta (Iranian mountain viper); Agkistrodon halys (Caucasian pitviper); Pseudocerastes persicus (Persian horned viper, Shfifon)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Iran

Region of use: Middle East

WHO prequalification: No

Polyvalent Snake Antivenom - Equine (National Antivenom & Vaccine Production Center, Saudi Arabia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1351

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Bitis arietans (Puff adder); Cerastes cerastes (Horned viper, Saharan horned viper); Echis carinatus (Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Naja haje (Egyptian cobra); Walterinnesia aegyptia (Desert cobra, Peten); Bitis caudalis (Horned Adder); Bitis gabonica (East African Gaboon viper); Naja nigricollis (Black-necked spitting cobra); Naja naja (Indian cobra, Spectacled cobra); and Naja melanoleuca (Black & white cobra, Forest cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Saudi Arabian Antivenom and Vaccine Production Center (AVCP) Polyvalent Snake Antivenom (https://antivenom-center.com/?page_id=77) is a refined and highly purified preparation containing the F(ab')2 fractions of immunoglobulins raised against the venom of six terrestrial Saudi snakes namely: Bitis arietans (Puff adder); Cerastes cerastes (Horned viper, Saharan horned viper); Echis carinatus (Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Naja haje (Egyptian cobra); Walterinnesia aegyptia (Desert cobra, Peten) (http://www.antivenoms.toxinfo.med.tum.de/resources/antivenom_saudiarabia-avpc-polyvalentsnake_2011-07-05.pdf) (https://www.sjfms.org/text.asp?2019/2/2/21/309347). The antivenom has been shown to neutralise the haemorrhagic and myonecrotic activity of viper snake venom, as well as the neurotoxic and cardiotoxic effects of elapid snake venom. Its efficacy against a number of Middle Eastern snakes including: Bitis caudalis (Horned Adder); Bitis gabonica (East African Gaboon viper); Naja nigricollis (Black-necked spitting cobra); Naja naja (Indian cobra, Spectacled cobra); and Naja melanoleuca (Black & white cobra, Forest cobra) has also been proven (http://www.antivenoms.toxinfo.med.tum.de/resources/antivenom_saudiarabia-avpc-polyvalentsnake_2011-07-05.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: National Antivenom and Vaccine Production Centre (NAVPC), Saudi Arabia

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bitis arietans; Cerastes cerastes; Echis borkini; Echis coloratus; Naja arabica; Walterinnesia aegyptia
Snake species *(Sources: other)*	**Bitis arietans (Puff adder); Cerastes cerastes (Horned viper, Saharan horned viper); Echis carinatus (Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Naja haje (Egyptian cobra); Walterinnesia aegyptia (Desert cobra, Peten)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Saudi Arabia
Regions	Middle East

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Cerastes gasperettii; Echis omanensis; Naja haje; Walterinnesia morgani

	Tested in	Effective against (any efficacy data)
Snake species *(Sources: Other)*	Bitis arietans (Puff adder); Cerastes cerastes (Horned viper, Saharan horned viper); Echis carinatus (Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Naja haje (Egyptian cobra); Walterinnesia aegyptia (Desert cobra, Peten); Bitis caudalis (Horned Adder); Bitis gabonica (East African Gaboon viper); Naja nigricollis (Black-necked spitting cobra); Naja naja (Indian cobra, Spectacled cobra); and Naja melanoleuca (Black & white cobra, Forest cobra)	Bitis arietans (Puff adder); Cerastes cerastes (Horned viper, Saharan horned viper); Echis carinatus (Saw-scaled viper); Echis coloratus (Burton's carpet viper, Palestine saw scaled viper); Naja haje (Egyptian cobra); Walterinnesia aegyptia (Desert cobra, Peten); Bitis caudalis (Horned Adder); Bitis gabonica (East African Gaboon viper); Naja nigricollis (Black-necked spitting cobra); Naja naja (Indian cobra, Spectacled cobra); and Naja melanoleuca (Black & white cobra, Forest cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding),Cytotoxic (tissue damage)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: United Arab Emirates; Kuwait; Qatar; Saudi Arabia

Region of use: Middle East

WHO prequalification: No

SnaFab5 (Padra Serum Alborz, Iran)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1341

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei (Caucasus viper); Echis carinatus (Saw-scaled viper); Pseudocerastes persicus (Persian horned viper, Shfifon); Gloydius halys caucasicus (Caucasian pitviper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

SnaFab 5 is a polyvalent antivenom containing equine immunoglobulin fragment F(ab')2, derived from the plasma of healthy equines, hyper immunized with snake venom. SnaFab 5 is indicated for neutralizing the venom of snakes in the provinces of Khorasan (Razavi, North, South), Golestan, Mazandaran, Semnan and Yazd as listed in the indications (https://padraserum.com/en/snafab-5-2/). Each ml of sterile SnaFab 5 solution can neutralise more than 50 LD50s from each species of snake, based on mice lethality experiments (https://padraserum.com/en/snafab-5-2/). It is approved for use in Iran and is being investigated in a Phase III randomized control trial (https://www.irct.ir/trial/41983).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Padra Serum Alborz

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase III, (Status: Unknown, February 2020-): *Phase 3, multi-center clinical trial for evaluation of two types of snake anti-venom* (CT number: IRCT20180515039672N2, CT source: http://en.irct.ir/trial/41983)

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis carinatus; Gloydius halys caucasicus; Macrovipera lebetina; Montivipera raddei; Pseudocerastes persicus
Snake species *(Sources: other)*	**Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei (Caucasus viper); Echis carinatus (Saw-scaled viper); Pseudocerastes persicus (Persian horned viper, Shfifon); Gloydius halys caucasicus (Caucasian pitviper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Iran
Regions	Middle East

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei (Caucasus viper); Echis carinatus (Saw-scaled viper); Pseudocerastes persicus (Persian horned viper, Shfifon); Gloydius halys caucasicus (Caucasian pitviper)	Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei (Caucasus viper); Echis carinatus (Saw-scaled viper); Pseudocerastes persicus (Persian horned viper, Shfifon); Gloydius halys caucasicus (Caucasian pitviper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Iran

Region of use: Middle East

WHO prequalification: No

SnaFab6 (Padra Serum Alborz, Iran)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1340

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei (Caucasus viper); Echis carinatus (Saw-scaled viper); Pseudocerastes persicus (Persian horned viper, Shfifon); Gloydius halys caucasicus (Caucasian pitviper); Naja oxiana (Central Asian cobra, Transcaspian cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

SnaFab 6 is a polyvalent antivenom containing equine immunoglobulin fragment F(ab')2, derived from the plasma of healthy equines, hyper immunized with snake venom. SnaFab 6 is indicated for neutralizing the venom of snakes in the provinces of Khorasan (Razavi, North, South), Golestan , Mazandaran, Semnan and Yazd as listed in the indications (https://padraserum.com/en/snafab-6/). Each ml of sterile SnaFab 6 solution can neutralise more than 50 LD50s from each species of snake, based on mice lethality experiments (https://padraserum.com/en/snafab-6/). It is approved for use in Iran and is being investigated in a Phase III randomized control trial (https://www.irct.ir/trial/41983).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Padra Serum Alborz

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase III, (Status: Active, February 2020-): *Phase 3, multi-center, randomized, two-arm, parallel, double blinded, active controlled for non-inferiority evaluation of efficacy and safety of snake anti-venom produced by Padra Serum Alborz in comparison with snake anti-venom produced by Razi Vaccine and Serum Research Institute in snakebite victims.* (CT number: IRCT20180515039672N2, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis carinatus; Gloydius halys caucasicus; Macrovipera lebetina; Montivipera raddei; Naja oxiana; Pseudocerastes persicus
Snake species *(Sources: other)*	**Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei (Caucasus viper); Echis carinatus (Saw-scaled viper); Pseudocerastes persicus (Persian horned viper, Shfifon); Gloydius halys caucasicus (Caucasian pitviper); Naja oxiana (Central Asian cobra, Transcaspian cobra)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Iran
Regions	Middle East

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei (Caucasus viper); Echis carinatus (Saw-scaled viper); Pseudocerastes persicus (Persian horned viper, Shfifon); Gloydius halys caucasicus (Caucasian pitviper); Naja oxiana (Central Asian cobra, Transcaspian cobra)	Macrovipera lebetina (Kufi, Levant viper, Levantine viper); Montivipera raddei (Caucasus viper); Echis carinatus (Saw-scaled viper); Pseudocerastes persicus (Persian horned viper, Shfifon); Gloydius halys caucasicus (Caucasian pitviper); Naja oxiana (Central Asian cobra, Transcaspian cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding),Cytotoxic (tissue damage)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Iran

Region of use: Middle East

WHO prequalification: No

Vipera palaestinae Equine Antiserum (Kamada Limited, Israel)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1408

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Daboia palaestinae (Palestine Viper, Tzefa)

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Unknown

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This antivenom currently used in Israel is a monovalent whole immunoglobulin. Since 2012, it has been produced by Kamada Pharmaceuticals, Beit-Kama, using Good Manufacturing Practice, according to methods developed by the Felsenstein (previously Rogof) Institute. It is more purified and less immunogenic than the original antivenom which was associated with anaphylaxis (4%) and serum sickness (4%) (https://pubmed.ncbi.nlm.nih.gov/32589364/). It is effective in neutralising the procoagulant effect of systemic Palestine viper envenomation (https://pubmed.ncbi.nlm.nih.gov/32589364/).In a retrospective evaluation of its efficacy in clinical settings, conducted in two paediatric hospitals in Israel, 50 ml dosing of the antivenom was found to be effective and safe for the treatment of systemic and progressive local manifestations of envenomation by Daboia palaestinae (https://pubmed.ncbi.nlm.nih.gov/28103732/). Similarly, successful use of the antivenom in preclinical settings, have been published (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6468471/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Kamada Ltd

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/32589364/https://pubmed.ncbi.nlm.nih.gov/32589364/https://pubmed.ncbi.nlm.nih.gov/30893807/https://pubmed.ncbi.nlm.nih.gov/28103732/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Daboia palaestinae
Snake species *(Sources: other)*	**Daboia palaestinae (Palestine Viper, Tzefa)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Israel
Regions	Middle East

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Daboia palaestinae (Palestine Viper, Tzefa)	Daboia palaestinae (Palestine Viper, Tzefa)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Israel

Region of use: Middle East

WHO prequalification: No

Central Asia

Monovalent serum against snake venom gyurza (UzbioPharm LLC, Uzbekistan)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1335

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Macrovipera lebetina (Kufi, Levant viper, Levantine viper, gyurza)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Anti-snake serum is a blood protein fraction containing specific immunoglobulins, hyperimmunized with venoms of gyurza (Macrovipera lebetina) snake, purified and concentrated by one of the methods of peptic digestion and salt fractionation. Chloroform is added as a preservative at a concentration of up to 0.5% in the finished product, which is a clear or slightly opalescent, colorless or yellowish liquid (https://biocom.uz/serum-instructions/). It is produced by UzbioPharm, and approved for use in Uzbekistan, by the Uzbekistan Ministry of Health (https://biocom.uz/serum-instructions/). It has been shown to effectively inhibit the PLA2 toxins in the venom of M. lebetina, in preclinical studies (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7285993/), thus counteracting its hemorrhagic and cytotoxic systemic effects.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: UzbioPharm LLC

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/32550590/https://pubmed.ncbi.nlm.nih.gov/32550590/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Macrovipera lebetina
Snake species *(Sources: other)*	**Macrovipera lebetina (Kufi, Levant viper, Levantine viper, gyurza)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Uzbekistan
Regions	Central Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Macrovipera lebetina (Kufi, Levant viper, Levantine viper, gyurza)	Macrovipera lebetina (Kufi, Levant viper, Levantine viper, gyurza)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: PLA2s

Syndromic profiles: Haemorrhagic (bleeding),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Uzbekistan

Region of use: Central Asia

WHO prequalification: No

Polyvalent serum against snake venoms gyurza, efa, and cobra (UzbioPharm LLC, Uzbekistan)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1336

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Macrovipera lebetina (Kufi, Levant viper, Levantine viper, gyurza); Echis carinatus (Saw-scaled viper); Naja oxiana (Central Asian cobra, Transcaspian cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Anti-snake serum is a blood protein fraction containing specific immunoglobulins, hyperimmunized with venoms of gyurza (Macrovipera lebetina), Echis carinatus (Saw-scaled viper) and Naja oxiana (Central Asian cobra, Transcaspian cobra) snakes, purified and concentrated by one of the methods of peptic digestion and salt fractionation. Chloroform is added as a preservative at a concentration of up to 0.5% in the finished product, which is a clear or slightly opalescent, colorless or yellowish liquid (https://biocom.uz/serum-instructions/). It is produced by UzbioPharm, and approved for use in Uzbekistan, by the Uzbekistan Ministry of Health (https://biocom.uz/serum-instructions/). It has been shown to effectively inhibit the PLA2 toxins in the venom of M. lebetina, in preclinical studies (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7285993/), thus counteracting its hemorrhagic and cytotoxic systemic effects.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: UzbioPharm LLC

Preclinical results status: Available

Preclinical sources: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7285993/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Echis carinatus; Macrovipera lebetina; Naja oxiana
Snake species *(Sources: other)*	**Macrovipera lebetina (Kufi, Levant viper, Levantine viper, gyurza); Echis carinatus (Saw-scaled viper); Naja oxiana (Central Asian cobra, Transcaspian cobra)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Uzbekistan
Regions	Central Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Macrovipera lebetina (Kufi, Levant viper, Levantine viper, gyurza); Echis carinatus (Saw-scaled viper); Naja oxiana (Central Asian cobra, Transcaspian cobra)	Macrovipera lebetina (Kufi, Levant viper, Levantine viper, gyurza); Echis carinatus (Saw-scaled viper); Naja oxiana (Central Asian cobra, Transcaspian cobra)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: PLA2s

Syndromic profiles: Haemorrhagic (bleeding),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Uzbekistan

Region of use: Central Asia

WHO prequalification: No

South Asia

Daboia Russelii Mono (VINS Bioproducts Ltd, India)

Alternative name(s): Russell's Viper Antivenin

Chemical name: N/A

CAS number: N/A

PCR ID: 2019

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude venom: Daboia russelli

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Daboia Russelli Monospecific antivenom is a sterile preparation containing equine immunoglobulin fragments F(ab')2. Freeze dried powder when reconstituted to 10mL of Sterilized Water for Injections B.P. supplied along with the vial, each 1mL has capacity of specifically neutralizing the venom of the following species Daboia russelii siamensis. The antitoxic equine immunoglobulin and their derivatives are obtained from the serum of healthy equines hyperimmunized against Eastern Russell's Viper venom. (https://vinsbio.in/daboia-russelli-mono/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VINS Bioproducts

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Daboia russelii siamensis (Eastern Russell's Viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Daboia russelii siamensis (Eastern Russell's Viper)	Daboia russelii siamensis (Eastern Russell's Viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South Asia

WHO prequalification: No

Indian Snake Anti Venom - I.P (VINS Bioproducts Ltd, India)

Alternative name(s): Snake Venom Antiserum I.P. - Asia

Chemical name: N/A

CAS number: N/A

PCR ID: 1367

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Indian snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Snake Venom Antiserum Liquid and Lyophilized for India, Pakistan, Sri Lanka, Bangladesh and Nepal. Snake Venom Antiserum is a sterile preparation containing equine immunoglobulin fragments F (ab') 2. Freeze dried powder is reconstituted in 10ml of sterile water for injection I.P. supplied along with the vial. Each ml has power to specifically neutralize the venoms of following species of snakes: Indian Cobra (Naja naja) venom, Common Krait (Bangarus Caeruleus) venom, Russell's Viper (Vipera Russelli) venom and Saw scaled Viper (Echis Carinatus) venom (https://vinsbio.in/products/indian-snake-anti-venom/). It has been evaluated in a number of clinical trials. (http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=10478)(https://pubmed.ncbi.nlm.nih.gov/28574015/; https://pubmed.ncbi.nlm.nih.gov/32658754/; https://pubmed.ncbi.nlm.nih.gov/29892202/; https://pubmed.ncbi.nlm.nih.gov/29169382/; https://pubmed.ncbi.nlm.nih.gov/29147044/; https://pubmed.ncbi.nlm.nih.gov/28905944/; https://pubmed.ncbi.nlm.nih.gov/28510574/; https://pubmed.ncbi.nlm.nih.gov/28422078/; https://slctr.lk/trials/slctr-2016012; https://pubmed.ncbi.nlm.nih.gov/27136587/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VINS Bioproducts

Preclinical results status: Available

Preclinical sources: https://www.mdpi.com/2072-6651/14/3/168/htm

Evidence of clinical trials? Yes

Phase II/Phase III, (Status: Unknown, June 2016-): *A study of the safety of a Sri Lankan antivenom compared to Indian antivenom in patients with snakeb* (CT number: SLCTR/2016/012, CT source: https://slctr.lk/trials/slctr-2016-012)

Phase: N/A, (Status: Active, May 2015-): *study to find out the better anti snake venom protocol among two in hemotoxic snake bite* (CT number: CTRI/2015/05/005826, CT source: http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=9948)

Phase: N/A, (Status: Active, October 2019-): *Venomous Exposures by Native Organisms of Medical Significance* (CT number: CTRI/2019/10/021828, CT source: http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=37244)

Phase: N/A, (Status: Unknown, June 2015-): *Low dose Anti Snake Venom for the treatment of neurotoxic snake bite* (CT number: CTRI/2015/06/005893, CT source: http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=10478)

Phase II, (Status: Unknown, January 2011-): *Comparison of Two Dose Regimens of Snake Antivenom for the Treatment of Snake Bites Envenoming in Nepal* (CT number: NCT01284855, CT source: https://clinicaltrials.gov/show/NCT01284855)

Phase: N/A, (Status: Active, July 2010-): *To find appropriate dose of antivenom(low dose/high dose regimen) for common krait bite in Sri Lanka* (CT number: SLCTR/2010/006, CT source: https://slctr.lk/trials/slctr-2010-006)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus caeruleus; Daboia russelii; Echis carinatus; Naja naja
Snake species *(Sources: other)*	**Naja naja (Indian Cobra); Bangarus Caeruleus (Common Krait); Vipera Russelli (Russell's Viper); Echis Carinatus (Saw-scaled Viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja naja (Indian Cobra); Bangarus Caeruleus (Common Krait); Vipera Russelli (Russell's Viper); Echis Carinatus (Saw-scaled Viper)	Naja naja (Indian Cobra); Bangarus Caeruleus (Common Krait); Vipera Russelli (Russell's Viper); Echis Carinatus (Saw-scaled Viper)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Myanmar; Sri Lanka; India; Nepal; Pakistan; Bangladesh

Region of use: South Asia

WHO prequalification: No

Naja Kouthia Mono (VINS Bioproducts Ltd, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 2018

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom: Naja Kouthia (Monocellate cobra, Thai cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Naja kaoutjia Mono antivenom is a monospecific antivenin product developed by VINS Bioproducts, India, and comprised from F(ab)'2 immunoglobulin fragments obtained from the plasma of horses immunised with venom from Naja kaouthia (https://vinsbio.in/naja-kouthia-mono/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VINS Bioproducts

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Naja Kouthia (Monocellate cobra, Thai cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunisation

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja Kouthia (Monocellate cobra, Thai cobra)	Naja Kouthia (Monocellate cobra, Thai cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South Asia

WHO prequalification: No

Polyvalent Anti Snake Venom Serum I.P. (King Institute of Preventative Medicine and Research, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1368

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Indian snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Polyvalent snale antivenin I.P product is aimed at neutralising the venom from the "Big Four" Indian snakes. KIPMR restarted manufacturing this antivenom for Indian snakes in 2016 after a 16-year hiatus thanks to upgrading of the facility.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: King Institute of Preventive Medicine & Research

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus caeruleus; Daboia russelii; Echis carinatus; Naja naja
Snake species *(Sources: other)*	**Russell's viper (Daboia russelii); Indian cobra (Naja naja); Common krait (Bungarus caeruleus); Saw-scaled viper (Echis carinatus)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Unknown	Unknown
Snake family		
Risk category		Unknown

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India

Region of use: South Asia

WHO prequalification: No

Polyvalent Antisnake Venom Serum (National Institute of Health, Pakistan)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1304

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Daboia russelii (Indian Russell's viper, Russell's viper, South Asian Russell's viper); Echis carinatus (Saw-scaled viper)

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Anti-Snake venom serum is a polyvalent antivenom containing purified and concentrated immunoglobulins obtained from the serum of healthy horses immunized against the venoms of the following four common poisonous snakes of Pakistan namely: Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Daboia russelii (Indian Russell's viper, Russell's viper, South Asian Russell's viper); Echis carinatus (Saw-scaled viper). Developed and manufactured by the Pakistani National Institute of Health further product information can be found at https://www.nih.org.pk/wp-content/uploads/2018/04/anti-snake-venom.pdf.It has been investigated in a comparative cross-sectional cost and efficacy trial, where it was found to be nearly twice as effective and cheaper than the Indian polyvalent snake antivenom (https://pubmed.ncbi.nlm.nih.gov/24601191/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: National Institute of Health, Pakistan

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase: N/A, (Status: Results submitted, -): *Comparative cost and efficacy trial of Pakistani versus Indian anti snake venom* (CT number: N/A, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus caeruleus; Daboia russelii; Echis carinatus; Naja naja
Snake species *(Sources: other)*	**Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Daboia russelii (Indian Russell's viper, Russell's viper, South Asian Russell's viper); Echis carinatus (Saw-scaled viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Pakistan
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Bungarus sindanus; Naja oxiana
Snake species *(Sources: Other)*	Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Daboia russelii (Indian Russell's viper, Russell's viper, South Asian Russell's viper); Echis carinatus (Saw-scaled viper)	Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Daboia russelii (Indian Russell's viper, Russell's viper, South Asian Russell's viper); Echis carinatus (Saw-scaled viper)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding),Cytotoxic (tissue damage)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Pakistan

Region of use: South Asia

WHO prequalification: No

Polyvalent Big Four Fab'2 antivenom (Incepta Vaccines, Bangladesh)

Alternative name(s): Snake Venom Antiserum BP

Chemical name: N/A

CAS number: N/A

PCR ID: 1964

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Vipera russelli (Russell's Viper); Echis carinatus (Saw-scaled viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 20-25°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Manufactured by Incepta Vaccines, Snake Venom Antiserum lyophilized is a refined and concentrated preparation of serum globulins for intravenous administration, containing equine immunoglobulin fragments F(ab')2, obtained from the plasma of healthy equines, hyperimmunized against venoms of the following snakes: Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Vipera russelli (Russell's Viper); Echis carinatus (Saw-scaled viper). In addition, it also contains the anti-microbial agent: cresol (http://inceptavaccine.com/product-details.php?pid=antivenom).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Incepta Vaccine

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Vipera russelli (Russell's Viper); Echis carinatus (Saw-scaled viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India; Bangladesh
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Vipera russelli (Russell's Viper); Echis carinatus (Saw-scaled viper)	Naja naja (Indian cobra, Spectacled cobra); Bungarus caeruleus (Indian krait); Vipera russelli (Russell's Viper); Echis carinatus (Saw-scaled viper)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South Asia

WHO prequalification: No

Polyvalent Snake Antivenin I.P. - Asia (Haffkine Biopharmaceutical Corporation Ltd, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1371

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Indian snakes

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This freeze dried polyvalent snake antivenin is useful in case of poisonous snake bites. As it comes in lyophilised form, it can be stored at comparatively high room temperature. On reconstitution, it is a solution of purified antibodies prepared from equine blood, and is available in vials along with water for injection. (https://www.vaccinehaffkine.com/products/antitoxins-sera/snake-antivenin-detail.html)(https://pubmed.ncbi.nlm.nih.gov/29234603/; https://pubmed.ncbi.nlm.nih.gov/28422078/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Haffkine Biopharmaceutical Corporation

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus caeruleus; Daboia russelii; Echis carinatus; Naja naja
Snake species *(Sources: other)*	**Indian Cobra (Naja naja), Common krait (Bangarus caeruleus), Russell's Viper (Vipera russellii) and Saw Scaled Viper (Echis carinatus)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Indian Cobra (Naja naja), Common krait (Bangarus caeruleus), Russell's Viper (Vipera russellii) and Saw Scaled Viper (Echis carinatus)	Indian Cobra (Naja naja), Common krait (Bangarus caeruleus), Russell's Viper (Vipera russellii) and Saw Scaled Viper (Echis carinatus)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India

Region of use: South Asia

WHO prequalification: No

SIIPL-01 Polyvalent Anti-snake Venom Serum (Serum Institute, India)

Alternative name(s): Snake Antivenom Serum, I.P. (Lyophilised)

Chemical name: N/A

CAS number: N/A

PCR ID: 1960

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Naja naja (Indian Cobra); Echis carinatus (Saw-scaled Viper); Daboia russelii (Russel's Viper); Bungarus caeruleus (Common Krait)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Vial indicates store in cool dark places

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The polyvalent anti-snake venom serum is a polyspecific antivenin product manufactured by the Serum Institute of India, and comprises of F(ab)'2 immunoglobulin fragments derived from the plasma of horses immunised with the venom of the big four snakes in India, including - Naja naja (Indian Cobra), Echis carinatus (Saw-scaled Viper), Daboia russelii (Russel's Viper) and Bungarus caeruleus (Common Krait) (https://www.seruminstitute.com/product_ind_antisnake.php). It's efficacy for the neutralisation of local and systemic envenomation by these snake species has been shown in pre-clinically (https://pubmed.ncbi.nlm.nih.gov/35324665/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Serum Institute of India (SII)

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/35324665/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Naja naja (Indian Cobra); Echis carinatus (Saw-scaled Viper); Daboia russelii (Russel's Viper); Bungarus caeruleus (Common Krait)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunisation

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus caeruleus (Common Krait); Bungarus ceylonicus (Ceylon krait); Bungarus fasciatus (Banded krait); Daboia russelii (Russel's Viper); Echis carinatus (Saw-scaled Viper); Hypnale hypnale (Hump-nosed pitviper); Naja naja (Indian Cobra); Ophiophagus hannah (Hamadryad, King cobra); Trimeresurus spp.	Bungarus caeruleus (Common Krait); Bungarus ceylonicus (Ceylon krait); Bungarus fasciatus (Banded krait); Daboia russelii (Russel's Viper); Echis carinatus (Saw-scaled Viper); Hypnale hypnale (Hump-nosed pitviper); Naja naja (Indian Cobra); Ophiophagus hannah (Hamadryad, King cobra); Trimeresurus spp.
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South Asia

WHO prequalification: No

Snake Antivenin (Polyvalent) IP (Biological E Limited, India)

Alternative name(s): Polyvalent Snake Antivenin - Asia

Chemical name: N/A

CAS number: N/A

PCR ID: 1370

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Indian snakes

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This snake antivenin(Polyvalent) IP is a refined, equine antivenom. It is indicated for passive immunization against snakebite envenoming and comes in Liquid & Lyophilized 10 mL Vial (https://www.biologicale.com/pdf/Product_Sera_List.pdf)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Biological E Limited

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus caeruleus; Daboia russelii; Echis carinatus; Naja naja
Snake species *(Sources: other)*	**Naja naja (Indian Cobra); Bungarus caeruleus (Common Krait); Vipera russelli (Russell's Viper); Echis carinatus (Saw Scaled Viper)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja naja (Indian Cobra); Bungarus caeruleus (Common Krait); Vipera russelli (Russell's Viper); Echis carinatus (Saw Scaled Viper)	Naja naja (Indian Cobra); Bungarus caeruleus (Common Krait); Vipera russelli (Russell's Viper); Echis carinatus (Saw Scaled Viper)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India

Region of use: South Asia

WHO prequalification: No

Snake venom antiserum I.P. (Premium Serums and Vaccines Pvt. Ltd., India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1366

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Indian snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The I.P. antiserum is a Lyophilized Polyvalent enzyme refined equine immunoglobulins targetting the Big Four snakes in India. (https://www.premiumserums.com/mainproduct.html#)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Premium Serums and Vaccines

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus caeruleus; Daboia russelii; Echis carinatus; Naja naja
Snake species *(Sources: other)*	**Naja naja (Indian Cobra); Bungarus caeruleus (Common Krait); Vipera russelii (Russell's viper); Echis carinatus (Saw scaled viper venom)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja naja (Indian Cobra); Bungarus caeruleus (Common Krait); Vipera russelii (Russell's viper); Echis carinatus (Saw scaled viper venom)	Naja naja (Indian Cobra); Bungarus caeruleus (Common Krait); Vipera russelii (Russell's viper); Echis carinatus (Saw scaled viper venom)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: India

Region of use: South Asia

WHO prequalification: No

V-ASV polyvalent antivenom (Virchow Biotech, India)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1937

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Naja naja (Indian Cobra); Daboia russelli (Russel's Viper); Echis carinatus (Saw-scaled Viper); Bungarus caeraleus (Common krait)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

V-ASV is a polyvalent antivenin product developed by Virchow Biotech, India, and indicated for the treatment of local and systemic envenomation by the big four Indian venomous snakes including - Naja naja (Indian Cobra); Daboia russelli (Russel's Viper); Echis carinatus (Saw-scaled Viper); Bungarus caeraleus (Common krait) (http://virchowbiotech.com/plasma.php). It consists of F(ab)'2 immunoglobulin fragments obtained from the plasma of horses immunized with the venom of these snakes obtained from India. It preclinical efficacy has been investigated in a comparative study with other second generation antivenoms against India's big four, and found to be effective albeit less effective than the others in terms of in vitro venom recognition (https://pubmed.ncbi.nlm.nih.gov/35324665/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Virchow Biotech

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/35324665/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Naja naja (Indian Cobra); Daboia russelli (Russel's Viper); Echis carinatus (Saw-scaled Viper); Bungarus caeraleus (Common krait)**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	India
Regions	South Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja naja (Indian Cobra); Daboia russelli (Russel's Viper); Echis carinatus (Saw-scaled Viper); Bungarus caeraleus (Common krait)	Naja naja (Indian Cobra); Daboia russelli (Russel's Viper); Echis carinatus (Saw-scaled Viper); Bungarus caeraleus (Common krait)
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South Asia

WHO prequalification: No

South East Asia

Anti-Viper antivenom - Russell's viper (Myanmar Pharmaceutical Factory (MPF)/Burma Pharmaceutical Industry (BPI), Myanmar)

Alternative name(s): Viper antivenom BPI

Chemical name: N/A

CAS number: N/A

PCR ID: 1410

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude Daboia Siamensis venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This antivenom, for Daboia Siamensis envenoming was developed by the Burma Pharmaceutical Industry (BPI) - initially it was developed in a liquid form, but it has been redeveloped into it's current lyophilized state through a 4-year collaborative initiative between institutions in Myanmar and Australia entitled the Myanmar Snakebite project. Antivenom production facilities have improved resulting in the production of a new monospecific F(ab)'2 antivenom. The current dosing strategy is based on unpublished results of pre-clinical testing and stratified into two doses according to absence or presence of clinical features of severity at presentation (80 mL and 160 mL, respectively). No clinical trial data or post marketing data has been published to support the efficacy or toxicity of these recommended doses (https://pubmed.ncbi.nlm.nih.gov/33196672/).However, a clinical trial is currently underway to determine an effective and safe dose of the new lyophilised viper antivenom currently in use to treat Russell’s viper envenoming in Myanmar (https://clinicaltrials.gov/ct2/show/NCT04210141).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Myanmar Pharmaceutical Factory (MPI)/BPI

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase II, (Status: Unknown, December 2019-): *Optimal Dose of Antivenom for Daboia Siamensis Envenomings* (CT number: NCT04210141, CT source: https://clinicaltrials.gov/show/NCT04210141)

Production/source

	Derived from
Snake species *(Source: WHO)*	Daboia siamensis
Snake species *(Sources: other)*	**Daboia siamensis**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Myanmar
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Daboia siamensis	Daboia siamensis
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Myanmar

Region of use: South East Asia

WHO prequalification: No

B. multicinctus and B. candidus antivenom (Vietnam Poison Control Center, Hanoi Medical University)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 2012

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude B. multicinctus and B. candidus venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

In northern Vietnam, a vast majority of the most severely envenomed patients are bitten by Bungarus multicinctus. This antivenom has been produced using the venoms of both Bungarus candidus and B. multicinctus snakes, and is used to treat envenomation by B. multicinctus, having shown clinical efficacy and a lack of severe adverse reactions. (https://link.springer.com/article/10.1007/s13181-010-0051-4, https://clinicaltrials.gov/ct2/show/NCT00811239)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Hanoi Medical University

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase I, (Status: Unknown, March 2004-December 2006): *A Controlled Clinical Trial on The Use of a Specific Antivenom Against Envenoming by Bungarus Multicinctus* (CT number: NCT00811239, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Bungarus candidus; Bungarus multicinctus**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus candidus; Bungarus multicinctus	Bungarus candidus; Bungarus multicinctus
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Vietnam

Region of use: South East Asia

WHO prequalification: No

Banded krait antivenin, Bungarus fasciatus monovalent antivenom - BFMAV (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): BFMAV

Chemical name: N/A

CAS number: N/A

PCR ID: 1403

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Bungarus fasciatus (Banded krait)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Banded krait antivenin is a monovalent antivenom developed by the Queen Saovabha Memorial Institute of the Thai Red Cross to be used for the treatment of local and systemic envenomation by Bungarus fasciatus (Banded krait) (http://nvi.ddc.moph.go.th/e-books/qsmi.pdf). It is being investigated in a Phase II/III randomised trial comparing its efficacy with that of polyvalent antivenins developed by the same developer (https://www.thaiclinicaltrials.org/show/TCTR20210826004). Its efficacy has been proven in preclinical studies (https://pubmed.ncbi.nlm.nih.gov/10091133/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/10091133/

Evidence of clinical trials? Yes

Phase II/III, (Status: Active, -): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus fasciatus
Snake species *(Sources: other)*	**Bungarus fasciatus (Banded krait)**
Snake family	**Elapidae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	Thailand
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus fasciatus (Banded krait)	Bungarus fasciatus (Banded krait)
Snake family		Elapidae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Thailand

Region of use: South East Asia

WHO prequalification: No

BioSave - Serum Anti Bisa Ular Polivalen (PT Bio Farma (Persero), Indonesia)

Alternative name(s): SABU

Chemical name: N/A

CAS number: N/A

PCR ID: 1373

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

BIOSAVE is a purified antiserum produced from equine plasma, providing immunity against snake venoms that are neurotoxic and haemotoxic, of which the snakes are widely found in Indonesia. It is effective against the venoms of Naja sputatrix, Bungarus fasciatus and Agkistrodon rhodostoma. It is produced by Biofarma, in Indonesia.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: PT Bio Farma

Preclinical results status: Available

Preclinical sources: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5116744/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus fasciatus; Calloselasma rhodostoma; Naja sputatrix
Snake species *(Sources: other)*	**Naja sputatrix; Bungarus fasciatus; Agkistrodon rhodostoma**
Snake family	**Viperidae,Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Indonesia
Regions	South East Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja sputatrix; Bungarus fasciatus; Agkistrodon rhodostoma	Naja sputatrix; Bungarus fasciatus; Agkistrodon rhodostoma
Snake family		Viperidae,Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Indonesia

Region of use: South East Asia

WHO prequalification: No

Bungarus candidus Antivenom (Venom Research Unit, University of Medicine and Pharmacy Ho Chi Minh City, Vietnam)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1951

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Bungarus candidus (Blue krait, Malayan krait)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This monospecific antivenom is for use in envenomation by Bungarus candidus venom, and has been developed by the Venom Research Unit University of Medicine and Pharmacy in Vietnam. (http://www.antivenoms.toxinfo.med.tum.de/productinfo/BUNGARUS_CANDIDUS_ANTIVENOM.html) (https://www.sciencedirect.com/science/article/pii/S0001706X21000127?via%3Dihub)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VRU, University of Medicine and Pharmacy, Vietnam

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Phase I/Phase II, (Status: Unknown, December 2008-): *A Controlled Clinical Trial on The Use of a Specific Antivenom Against Envenoming by Bungarus Multicinctus* (CT number: NCT00811239, CT source: http://clinicaltrials.gov/show/NCT00811239)

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Bungarus candidus (Blue krait, Malayan krait)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus candidus (Blue krait, Malayan krait)	Bungarus candidus (Blue krait, Malayan krait)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South East Asia

WHO prequalification: No

Bungarus candidus Monospecific Antivenom (Venom Research & Antivenom Production Unit, National Poison Control Center, Vietnam)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1945

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Bungarus candidus (Blue krait, Malayan krait)

Route of administration: Intravenous

Ig format: Unknown

Ig final product type/preparation: Unknown

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This monospecific antivenom was developed by the Venom Research and Antivenom Production Unit of the National Poison Control Center, Vietnam, against the venom of the Malayan krait, and it has been shown to be effective in treating local and systemic envenomation by Bungarus candidus in Malayan victims of envenomation (https://www.sciencedirect.com/science/article/pii/S0041010110002552)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Venom Research & Antivenom Production Unit, Vietnam

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? No

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Bungarus candidus (Blue krait, Malayan krait)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine imunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus candidus (Blue krait, Malayan krait)	Bungarus candidus (Blue krait, Malayan krait)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South East Asia

WHO prequalification: No

Calloselasma rhodostoma - Malayan Pit Viper Antivenom (Venom Research Unit, University of Medicine and Pharmacy Ho Chi Minh City, Vietnam)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1952

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Calloselasma rhodostoma (Malayan Pit Viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The monospecific Calloselasma rhodostoma antivenom has been developed by the Venom Research Unit, University of Medicine and Pharmacy Ho Chi Minh City, for treatment of local and systemic envenomation by the Malayan pitviper (https://pubmed.ncbi.nlm.nih.gov/33485869/). There is little publicly available information about its preclinical or clinical efficay.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VRU, University of Medicine and Pharmacy, Vietnam

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Calloselasma rhodostoma (Malayan Pit Viper)**
Snake family	**Viperidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Calloselasma rhodostoma (Malayan Pit Viper)	Calloselasma rhodostoma (Malayan Pit Viper)
Snake family		Viperidae
Risk category		Category 1 (Highest Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: SVMPs,PLA2s,SVSPs

Syndromic profiles: Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South East Asia

WHO prequalification: No

Cobra Antivenin (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1363

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Naja kaouthia (Monocellate cobra, Thai cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Cobra antivenin developed by the Queen Saovabha Memorial Institute of the Thai Red Cross, is a monovalent antivenom raised for th treatmen tof the neurotoxic effects of systemic Naja kaouthia (Monocellate cobra, Thai cobra) envenomation. It has been shown to be effective clinically (https://pubmed.ncbi.nlm.nih.gov/11990132/). It has also been investigated for its efficacy in treating envenomation by sea snake - Lapemis hardwickii and was found to be effective (https://pubmed.ncbi.nlm.nih.gov/11491464/). It is currently a part of a Phase II/III clinical trial testing its efficacy against that of a novel polyvalent vaccine being developed by the same developer (https://www.thaiclinicaltrials.org/show/TCTR20210826004).The Cobra antivenin is officially available in Thailand and Malaysia and unofficially in Indonesia and Lao PDR (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/11491464/

Evidence of clinical trials? Yes

Phase II/III, (Status: Active, -): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Naja kaouthia
Snake species *(Sources: other)*	**Naja kaouthia (Monocellate cobra, Thai cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Thailand
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Naja siamensis; Naja sumatrana
Snake species *(Sources: Other)*	Naja kaouthia (Monocellate cobra, Thai cobra); Lapemis hardwickii (Spine-bellied sea snake)	Naja kaouthia (Monocellate cobra, Thai cobra); Lapemis hardwickii (Spine-bellied sea snake); paraspecificity against Naja siamensis (Indochinese spitting cobra, Siamese spitting cobra) and Naja sumatrana (Equatorial spitting cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Malaysia; Thailand

Region of use: South East Asia

WHO prequalification: No

Green Pit Viper Antivenin (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): Trimeresurus albolabris Monovalent Antivenom (TaMAV) - Thailand

Chemical name: N/A

CAS number: N/A

PCR ID: 1308

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Trimeresurus albolabris (Green pit viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Green Pit viper Antivenin developed by the Queen Saovabha Memorial Institute, Thailand is indicated for treatment of systemic envenomation by the green pit viper (Trimeresurus albolabris) (http://nvi.ddc.moph.go.th/e-books/qsmi.pdf). It is one of the products currently being investigated within a comparative Phase II/III clinical trial (https://www.thaiclinicaltrials.org/show/TCTR20210826004) to determine efficacy and effective dosing for a polyvalent Thai anti-venom candidate. It is also being investigated in a Phase IV clinical trial of its efficacy in treatment of green pit viper envenomation (https://www.thaiclinicaltrials.org/show/TCTR20211027005).Incidence of hypersensitivity reactions following the use of the green pit viper antivenin was compared with that from the Agkistrodon Halys antivenom in a recent clinical review, which showed that the green pit viper antivenin had a higher rate of hypersensitivity reactions (4.7%) compared with 1.4% attributed to the Agkistrodon Halys antivenom (https://pubmed.ncbi.nlm.nih.gov/28657429/). Another preclinical study in mice showed that the Agkistrodon Halys antivenom had a superior neutralisation power over the Green pit viper antivenin for treating green pit viper envenomation (https://pubmed.ncbi.nlm.nih.gov/22302910/). The Green pit viper antivenin is effective in neutralising the hemorrhagic as well as procoagulant effects of multiple green pit viper sub-species, as shown by another study (https://pubmed.ncbi.nlm.nih.gov/34600909/)The Green Pit Viper antivenom is officially available in Thailand, Malaysia and Indonesia and unofficially in Lao PDR (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/34600909/https://pubmed.ncbi.nlm.nih.gov/22302910/

Evidence of clinical trials? Yes

Phase IV, (Status: Active, October 2021-): *Effects of antivenom for local limb swelling reduction in patients envenomated by green pit viper: d* (CT number: TCTR20211027005, CT source: www.thaiclinicaltrials.org/show/TCTR20211027005)

Phase II/III, (Status: Active, September 2021-March 2023): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Cryptelytrops albolabris; Trimeresurus albolabris
Snake species *(Sources: other)*	**Trimeresurus Albolabris (Green pit viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Thailand
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Cryptelytrops erythrurus; Cryptelytrops insularis; Cryptelytrops macrops; Cryptelytrops purpureomaculatus; Protobothrops mangshanensis; Trimeresurus erythrurus; Trimeresurus insularis; Trimeresurus macrops; Trimeresurus purpureomaculatus
Snake species *(Sources: Other)*	Trimeresurus Albolabris; Trimeresurus macrops; Trimeresurus popeiorum; Trimeresurus hageni; Trimeresurus purpureomaculatus; Trimeresurus kanburiensis	Trimeresurus Albolabris, Trimeresurus macrops, Trimeresurus popeiorum; Trimeresurus hageni; Trimeresurus purpureomaculatus; Trimeresurus kanburiensis; Protobothrops mangshanensis; Trimeresurus erythrurus; Trimeresurus insularis
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Malaysia; Indonesia; Thailand

Region of use: South East Asia

WHO prequalification: No

Haemato-polyvalent snake antivenom - HPAV (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1309

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper); Calloselasma rhodostoma (Malayan pitviper); Trimeresurus albolabris (Green pit viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Hemato-polyvalent snake antivenom (HPAV) developed by the Queen Saovabha Memorial Institute, is a polyvalent product against the venoms of three medically important vipers in Thailand, namely - Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper); Calloselasma rhodostoma (Malayan pitviper); and Trimeresurus albolabris (Green pit viper) and has been shown to be effective in neutralising venoms from these snakes, in preclinical studies (https://pubmed.ncbi.nlm.nih.gov/33287378/).It has been shown to be effective in the cross-neutralisation of both the procoagulant and hemorrhagic action of a number of southeast Asian viper venoms including - Hypnale hypnale (Hump-nosed pitviper); Trimeresurus purpureomaculatus (Mangrove pitviper, Shore pitviper); Trimeresurus hageni (Hagen's pit viper, Hagens Bambusotter); Trimeresurus fucatus (https://pubmed.ncbi.nlm.nih.gov/24384454/) (https://pubmed.ncbi.nlm.nih.gov/33287378/). It is currently being investigated in a Phase II/III comparative clinical trial of its efficacy vs that of its monospecific counterparts (https://www.thaiclinicaltrials.org/show/TCTR20210826004)The Haemato-Polyvalent antivenom is officially available in Thailand and Malaysia and unofficially in Lao PDR (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/33287378/https://pubmed.ncbi.nlm.nih.gov/24384454/

Evidence of clinical trials? Yes

Phase II/III, (Status: Unknown, September 2021-March 2023): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: www.thaiclinicaltrials.org/show/TCTR20210826004)

Production/source

	Derived from
Snake species *(Source: WHO)*	Calloselasma rhodostoma; Cryptelytrops albolabris; Daboia siamensis; Trimeresurus albolabris
Snake species *(Sources: other)*	**Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper); Calloselasma rhodostoma (Malayan pitviper); Trimeresurus albolabris (Green pit viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Thailand
Regions	South East Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Cryptelytrops insularis; Cryptelytrops purpureomaculatus; Trimeresurus insularis; Trimeresurus purpureomaculatus
Snake species *(Sources: Other)*	Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper); Calloselasma rhodostoma (Malayan pitviper); Trimeresurus albolabris (Green pit viper); Hypnale hypnale (Hump-nosed pitviper); Trimeresurus purpureomaculatus (Mangrove pitviper, Shore pitviper); Trimeresurus hageni (Hagen's pit viper, Hagens Bambusotter); Trimeresurus fucatus	Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper); Calloselasma rhodostoma (Malayan pitviper); Trimeresurus albolabris (Green pit viper); Hypnale hypnale (Hump-nosed pitviper); Trimeresurus purpureomaculatus (Mangrove pitviper, Shore pitviper); Trimeresurus hageni (Hagen's pit viper, Hagens Bambusotter); Trimeresurus fucatus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Malaysia; Thailand

Region of use: South East Asia

WHO prequalification: No

King cobra antivenin (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1374

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Ophiophagus hannah (king cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

King cobra antivenin developed by the Queen Saovabha Memorial Institute of Thai Red Cross Society is a monovalent antivenom effective against neutralising the neurotoxic effects of the king cobra (Ophiophagus hannah) (http://nvi.ddc.moph.go.th/e-books/qsmi.pdf). It is investigated within a Phase II/III trial comparing its efficacy against that of polyvalent antivenoms manufactured by the same developer (https://www.thaiclinicaltrials.org/show/TCTR20210826004).King Cobra antivenin is officially available in Thailand and Malaysia and unofficially in Indonesia (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase II/III, (Status: Active, -): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Ophiophagus hannah
Snake species *(Sources: other)*	**Ophiophagus hannah (king cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Thailand
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Ophiophagus hannah (king cobra)	Ophiophagus hannah (king cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Thailand; Malaysia

Region of use: South East Asia

WHO prequalification: No

Malayan krait antivenin (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1402

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Bungarus candidus (Blue krait, Malayan krait)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Malayan krait antivenin is a monovalent antivenom developed by the Queen Saovabha Memorial Institute of the Thai Red Cross to be used for the treatment of local and systemic envenomation by Bungarus candidus (http://nvi.ddc.moph.go.th/e-books/qsmi.pdf). It is being investigated in a Phase II/III randomised trial comparing its efficacy with that of polyvalent antivenins developed by the same developer (https://www.thaiclinicaltrials.org/show/TCTR20210826004).It has also been shown in preclinical studies that the Malayan krait antivenin is capable of neutralising the venom of the two other kraits found in Thailand, including the banded krait (Bungarus fasciatus) and the red-header krait (Bungarus flaviceps) (https://pubmed.ncbi.nlm.nih.gov/10091133/)The Malayan Krait antivenin is officially available in Thailand and unofficially in Indonesia and Lao PDR (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/10091133/

Evidence of clinical trials? Yes

Phase II/III, (Status: Active, -): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus candidus
Snake species *(Sources: other)*	**Bungarus candidus (Blue krait, Malayan krait)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Malaysia
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus candidus (Blue krait, Malayan krait); Bungarus fasciatus (banded krait); Bungarus flaviceps (red-header krait)	Bungarus candidus (Blue krait, Malayan krait); Bungarus fasciatus (banded krait); Bungarus flaviceps (red-header krait)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: SVMPs,PLA2s,SVSPs,LAAO

Syndromic profiles: Haemorrhagic (bleeding),Cytotoxic (tissue damage),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Thailand

Region of use: South East Asia

WHO prequalification: No

Malayan Pit Viper Antivenin (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1404

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom; Thai snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

A randomised Phase II/III trial testing the Haemato-polyvalent and Neuro-polyvalent products against the monovalent antivenom against Russell's viper, green pit viper, or Malayan pit viper (hematoxic) and monovalent antivenom against cobra, king cobra, Malayan krait, or banded krait (neurotoxic) has been submitted for board/ethics approval in Thailand to evaluate efficacy and dosing (https://www.thaiclinicaltrials.org/show/TCTR20210826004).The α-gal epitope is present on horse-derived IgG in polyclonal IgG preparations of snake antivenoms and recently the reactivity of sIgE in individuals with α-gal allergy to red meat has been demonstrated against different antivenoms including monovalent green pit viper and Malayan pit viper antivenom from QSMI, Bangkok, Thailand, using basophil activation tests (https://pubmed.ncbi.nlm.nih.gov/27775867/). A recent study investigated the hypothesis whether sIgE against α-gal is responsible for hypersensitivity reactions in Laotian patients treated with snake antivenom from QSMI (https://pubmed.ncbi.nlm.nih.gov/32776003/).Malayan Pit Viper antivenom is officially available in Thailand, Malaysia and Vietnam and unofficially in Lao PDR (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Yes

Phase II/Phase III, (Status: Unknown, September 2021-March 2021): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Calloselasma rhodostoma
Snake species *(Sources: other)*	**Calloselasma Rhodostoma (Malayan pit viper)**
Snake family	**Viperidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	Malaysia
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Calloselasma Rhodostoma (Malayan pit viper)	Calloselasma Rhodostoma (Malayan pit viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: High toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Thailand; Malaysia; Vietnam

Region of use: South East Asia

WHO prequalification: No

Monovalent caprine antivenom against C. rhodostoma (Twyford Pharmaceutical)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 2011

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Calloselasma rhodostoma (Malayan pit viper)

Route of administration: Intravenous

Ig format: Unknown

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Manufactured by Twyford Pharmaceutical, Thailand, the liquid monovalent caprine antivenom is marketed for treatment of Calloselasma rhodostoma (Malayan pit viper) snakebite envenoming (https://pubmed.ncbi.nlm.nih.gov/3080048/). It obtained raised from the blood of goats hyperimmunised with the venom from the Malayan pit viper (i.e. of caprine origin), and its pharmacokinetic properties have been investigated showing a shorter elimination half life, compared with similar antivenom developed by the Government Pharmaceutical Organization of Thailand (GPO) (https://pubmed.ncbi.nlm.nih.gov/2316795/).It was shown in a randomised comparative clinical trial of C. rhodostoma antivenom products, that both the Twyford and CPO antivenoms were effective in inhibiting the hemorrhagic effect of systemic C. rhodostoma envenomation (https://pubmed.ncbi.nlm.nih.gov/3538922/), however the GPO product produced less early anaphylactic reactions, compared with the Twyford vaccine.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Twyford Pharmaceutical

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/2316795/

Evidence of clinical trials? Yes

Phase I/II, (Status: Results submitted, -): *Randomized comparative trial of three monospecific antivenoms for bites by the Malayan pit viper (Calloselasma rhodostoma) in southern Thailand: clinical and laboratory correlations* (CT number: N/A, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Calloselasma rhodostoma (Malayan pit viper)**
Snake family	**Viperidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	Thailand
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent caprine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Calloselasma rhodostoma (Malayan pit viper)	Calloselasma rhodostoma (Malayan pit viper)
Snake family		Viperidae
Risk category		Category 1 (Highest Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Thailand

Region of use: South East Asia

WHO prequalification: No

Monovalent Naja philippinensis Cobra Antivenom (Biologicals Manufacturing Division of Research Institute for Tropical Medicine, Philippines)

Alternative name(s): PCAV - Purified Cobra Antivenom

Chemical name: N/A

CAS number: N/A

PCR ID: 1372

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude Naja philippinensis venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Purified Cobra Antivenin (PCAV) is a monovalent antivenom against the Philippine cobra (Naja philippinensis), a category 1 medically important snake endemic to the Philippines. It is housed by the RITM in the Philippines. PCAV is packaged in 5 mL ampoules containing 4.8 mL of antivenin which is capable of neutralizing 4.8 mg of venom. (https://academic.oup.com/trstmh/article/115/1/78/5908371?login=true, https://ritm.gov.ph/pcav-saving-lives-one-ampoule-at-a-time/)In 2019, the Biologicals Manufacturing Division of RITM received a PhP 1 million grant aimed at improving the production of PCAV. (https://ritm.gov.ph/bmd-receives-1m-peso-grant-to-improve-production-of-pcav/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Research Institute for Tropical Medicine

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/32945886/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Naja philippinensis
Snake species *(Sources: other)*	**Naja philippinensis**
Snake family	**Elapidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	Philippines
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Naja samarensis
Snake species *(Sources: Other)*	Samar cobra (Naja samarensis)	Naja philippinensis; Naja samarensis
Snake family		Elapidae
Risk category		Category 1 (Highest Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Philippines

Region of use: South East Asia

WHO prequalification: No

Naja kaouthia Antivenom (Venom Research Unit, University of Medicine and Pharmacy Ho Chi Minh City, Vietnam)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1953

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Naja kaouthia (Monocellate cobra, Thai cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The monospecific Naja kaouthia antivenom was developed by the Venom Research Unit, University of Medicine and Pharmacy Ho Chi Minh City and indicated for the treatment of local and systemic envenomation by the Vietnamese Naja kaouthia snake species. It is comprised of F(ab)'2 antibody fragments derived from the plasma of horses immunised with the venom of the Vietnamese Naja kaouthia (https://pubmed.ncbi.nlm.nih.gov/35622581/). It has been tested in a preclinical study comparing its efficacy with that of Naja kaouthia antivenoms produced in Thailand and Taiwan, and it was found to be more effective that both candidates in neutralising venom-induced cytotoxicity (https://pubmed.ncbi.nlm.nih.gov/35622581/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VRU, University of Medicine and Pharmacy, Vietnam

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/35622581/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Naja kaouthia (Monocellate cobra, Thai cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja kaouthia (Monocellate cobra, Thai cobra)	Naja kaouthia (Monocellate cobra, Thai cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: PLA2s,3FTxs

Syndromic profiles: Neurotoxic (paralysis),Cytotoxic (tissue damage)

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South East Asia

WHO prequalification: No

Naja siamensis Antivenom (Venom Research Unit, University of Medicine and Pharmacy Ho Chi Minh City, Vietnam)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1954

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Naja siamensis (Indochinese spitting cobra, Siamese spitting cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This antivenom, developed by the Venom Research Unit University of Medicine and Pharmacy in Vietnam is for use against envenomation by Naja siamensis (Indochinese spitting cobra, Siamese spitting cobra) (https://pubmed.ncbi.nlm.nih.gov/33485869/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VRU, University of Medicine and Pharmacy, Vietnam

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Naja siamensis (Indochinese spitting cobra, Siamese spitting cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunisation

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja siamensis (Indochinese spitting cobra, Siamese spitting cobra)	Naja siamensis (Indochinese spitting cobra, Siamese spitting cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South East Asia

WHO prequalification: No

Neuro-polyvalent snake antivenom (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): NPAV

Chemical name: N/A

CAS number: N/A

PCR ID: 1364

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Naja kaouthia (Thai monocellate cobra); Ophiophagus hannah (Hamadryad, King cobra); Bungarus candidus (Blue krait, Malayan krait); Bungarus fasciatus (banded krait)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Neuro-polyvalent snake antivenom (NPAV) is a polyvalent antivenom raised against venoms of four medically important cobras and kraits in Thailand, including Naja kaouthia (Thai monocellate cobra); Ophiophagus hannah (Hamadryad, King cobra); Bungarus candidus (Blue krait, Malayan krait); Bungarus fasciatus (banded krait) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3367981/). It is indicated for the treatment of systemic envenomation caused by the venoms of a range of Southeast Asian snakes - Naja, Bungarus and Ophiophagus hannah but less effective against the venoms of Naja from the India subcontinent and Africa, as well as the Asiatic N. philippinensis (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3367981/).It is being investigated in a Phase II/III trial for its efficacy compared with that of monovalent products from the same manufacturer (https://www.thaiclinicaltrials.org/show/TCTR20210826004). It has also been investigated for its cross-reactivity in treating Naja sumatrana (Equatorial spitting cobra) and found to be effective against the PLA2 and neurotoxins of these snakes (https://pubmed.ncbi.nlm.nih.gov/26026717/)Neuro-polyvalent antivenom is officially available in Thailand, Malaysia and Vietnam and unofficially in Lao PDR (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/26026717/

Evidence of clinical trials? Yes

Phase II/Phase III, (Status: Unknown, August 2021-): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: www.thaiclinicaltrials.org/show/TCTR20210826004)

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus candidus; Bungarus fasciatus; Naja kaouthia; Ophiophagus hannah
Snake species *(Sources: other)*	**Naja kaouthia (Thai monocellate cobra); Ophiophagus hannah (Hamadryad, King cobra); Bungarus candidus (Blue krait, Malayan krait); Bungarus fasciatus (banded krait)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Thailand; Malaysia
Regions	South East Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Naja siamensis; Naja sumatrana
Snake species *(Sources: Other)*	Naja kaouthia (Thai monocellate cobra); Ophiophagus hannah (Hamadryad, King cobra); Bungarus candidus (Blue krait, Malayan krait); Bungarus fasciatus (banded krait); Naja sumatrana (Equatorial spitting cobra)	Naja kaouthia (Thai monocellate cobra); Ophiophagus hannah (Hamadryad, King cobra); Bungarus candidus (Blue krait, Malayan krait); Bungarus fasciatus (banded krait); Naja sumatrana (Equatorial spitting cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: High toxicity toxins

Specific target toxin class: PLA2s

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Thailand; Malaysia; Vietnam

Region of use: South East Asia

WHO prequalification: No

Ophiophagus hannah Antivenom (Venom Research Unit, University of Medicine and Pharmacy Ho Chi Minh City, Vietnam)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1955

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Ophiophagus hannah (king cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This antivenom, developed by the Venom Research Unit University of Medicine and Pharmacy in Vietnam is for use against envenomation by Ophiophagus hannah (king cobra) (http://www.antivenoms.toxinfo.med.tum.de/productinfo/OPHIOPHAGUS_HANNAH_ANTIVENOM.html)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: VRU, University of Medicine and Pharmacy, Vietnam

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Ophiophagus hannah (king cobra)**
Snake family	**Elapidae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunisation

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Ophiophagus hannah (king cobra)	Ophiophagus hannah (king cobra)
Snake family		Elapidae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: South East Asia

WHO prequalification: No

Russell's viper antivenin (Queen Saovabha Memorial Institute, Thailand)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1409

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Daboia siamensis (Eastern Russell's viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Under 25ºC

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Russell's viper antivenin is a monovalent antivenom developed by the Queen Saovabha Memorial Institute of the Thai Red Cross to be used for the treatment of local and systemic envenomation by Daboia siamensis (Eastern Russell's viper) (http://nvi.ddc.moph.go.th/e-books/qsmi.pdf). It is being investigated in a Phase II/III randomised trial comparing its efficacy with that of polyvalent antivenins developed by the same developer (https://www.thaiclinicaltrials.org/show/TCTR20210826004). A recent preclinical study has established the broad geographical utility of this antivenom (https://pubmed.ncbi.nlm.nih.gov/31644526/)The Russell's viper antivenin is officially available in Thailand and unofficially in Lao PDR (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Queen Saovabha Memorial Institute

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/31644526/

Evidence of clinical trials? Yes

Phase II/III, (Status: Active, -): *Comparison of clinical outcomes between polyvalent and monovalent antivenoms: a pilot study* (CT number: TCTR20210826004, CT source: N/A)

Production/source

	Derived from
Snake species *(Source: WHO)*	Daboia siamensis
Snake species *(Sources: other)*	**Daboia siamensis (Eastern Russell's viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Thailand
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Daboia siamensis (Eastern Russell's viper)	Daboia siamensis (Eastern Russell's viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Thailand

Region of use: South East Asia

WHO prequalification: No

SAV-Naja (Institute of Vaccines and Biological Substances, Vietnam)

Alternative name(s): Huyết thanh kháng nọc rắn Hổ đất tinh chế; Refined cobra antivenom

Chemical name: N/A

CAS number: N/A

PCR ID: 1361

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Naja Kaouthia (Monocellate cobra, Thai cobra)

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Purified ground cobra (Naja kaouthia) antivenom developed by the Viet Nam Institute of Vaccines and Biological Substances is a colorless or pale yellow solution, derived from horse blood containing antibodies to ground cobra venom (https://ivac.com.vn/san-pham/5/21/huyet-thanh-khang-noc-ran-ho-dat-tinh-che/vien-vac-xin.html). Also called SAV-Naj, it is approved and indicated for treatment of cobra snakebite envenomation in Viet Nam.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Institute of Vaccines and Biological Substances, Vietnam

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Naja kaouthia
Snake species *(Sources: other)*	**Naja Kaouthia (Monocellate cobra, Thai cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja Kaouthia (Monocellate cobra, Thai cobra)	Naja Kaouthia (Monocellate cobra, Thai cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Vietnam

Region of use: South East Asia

WHO prequalification: No

SAV-Trimeresurus (Institute of Vaccines and Biological Substances, VietNam)

Alternative name(s): Huyết thanh kháng nọc rắn Lục tre tinh chế; Refined green bamboo snake antivenom

Chemical name: N/A

CAS number: N/A

PCR ID: 1310

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Trimeresurus albolabris (White-lipped pitviper)

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The Refined green bamboo snake antivenom developed by the Viet Nam Institute of Vaccines and Biological Substances is a monovalent, liquid solution, derived from horse blood containing antibodies to bamboo viper (Trimeresurus albolabris) venom (https://ivac.com.vn/san-pham/5/22/huyet-thanh-khang-noc-ran-luc-tre-tinh-che/vien-vac-xin.html). Also called SAV-Tri, it is approved and indicated for treatment of bamboo viper snakebite envenomation in Viet Nam. SAV-Tri is officially available in Vietnam and unofficially in Lao PDR (https://pubmed.ncbi.nlm.nih.gov/35296460/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Institute of Vaccines and Biological Substances, Vietnam

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Cryptelytrops albolabris; Trimeresurus albolabris
Snake species *(Sources: other)*	**Trimeresurus albolabris (White-lipped pitviper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Vietnam
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Trimeresurus albolabris (White-lipped pitviper)	Trimeresurus albolabris (White-lipped pitviper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Vietnam

Region of use: South East Asia

WHO prequalification: No

Siamese cobra antivenin (Myanmar Pharmaceutical Factory, Myanmar)

Alternative name(s): SAsPIM02; BPI Cobra Antivenom

Chemical name: N/A

CAS number: N/A

PCR ID: 1362

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Traditional antivenoms are derived from the plasma/serum of mammals – usually horses – hyperimmunized with selected snake venom(s). The plasma, which contains snake venom-specific immunoglobulins, is then isolated and purified, with immunoglobulins either left intact as whole Ig (IgG) format, or cleaved into F(ab')2 or F(ab) antibody fragments. Most antivenoms are available in liquid or freeze-dried format (to improve stability), and administered intravenously. Although traditional equine plasma derived antivenoms are expensive to develop, labour intensive, and highly immunogenic, often causing severe side effects such as serum sickness or anaphylactic shock, they are nonetheless relatively effective, and currently the only approved therapeutics for snakebite envenoming.This antivenom is an anti-cobra antivenom, produced by Myanmar Pharmaceutical Factory, and is for treatment of envenomation by Naja kaouthia (Siamese cobra). It is a monovalent, equine, lyophilised, intact immunoglobulin product.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Myanmar Pharmaceutical Factory (MPI)/BPI

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Naja kaouthia
Snake species *(Sources: other)*	**Naja siamensis**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Myanmar
Regions	South East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja siamensis	Naja siamensis
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Myanmar

Region of use: South East Asia

WHO prequalification: No

East Asia

Agkistrodon acutus antivenom - DaMAV-China (Shanghai Serum Bio-technology Co Ltd, China)

Alternative name(s): DaAV; +3C; Sharp-nosed Pit Viper antivenom

Chemical name: N/A

CAS number: N/A

PCR ID: 1412

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude Agkistrodon acutus venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Agkistrodon acutus antivenin is produced by Shanghai Serum Bio-technology Co in China, and has been found to have a neuroprotective effect following D. acutus envenomation, by attenuating brain edema. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5798054/). In 1970, Agkistrodon Halys Antivenin was approved by SFDAIn 1970, Agkistrodon Halys Antivenin was approved by SFDA (http://www.serum-china.com.cn/enprodetail/187.html)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Shanghai Serum Bio-Technology Co

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Deinagkistrodon acutus
Snake species *(Sources: other)*	**Agkistrodon acutus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	China
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Agkistrodon acutus	Agkistrodon acutus; Ovophis monticola; Trimeresurus stejnegeri
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: China

Region of use: East Asia

WHO prequalification: No

Agkistrodon halys antivenom - AhAV (Shanghai Serum Bio-technology Co Ltd, China)

Alternative name(s): +3C; Gloydius brevicaudus Antivenom (GbMAV); Gloydius brevicaudus (Short-Tailed Mamushi) antivenom

Chemical name: N/A

CAS number: N/A

PCR ID: 1419

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude Gloydius brevicaudus venom; Chinese snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Agkistrodon halys antivenin is developed by the Shanghai Serum Biotechnology Co, and is a monovalent antivenom for treatment of Agkistrodon halys envenomation. In safety studies it has been shown to have a low rate of adverse reactions, and that the majority of patients can be managed with use of this product. (https://pubmed.ncbi.nlm.nih.gov/28657429/). The antivenom of Agkistrodon halys is not made by injecting Agkistrodon halys venom into horses, but Gloydius brevicaudus (short-tailed pit viper) https://www.tandfonline.com/doi/full/10.1080/15563650.2022.2041200

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Shanghai Serum Bio-Technology Co

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Gloydius halys
Snake species *(Sources: other)*	**Gloydius brevicaudus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	China
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Agkistrodon halys; Gloydius brevicaudus	Agkistrodon halys; Gloydius brevicaudus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: China

Region of use: East Asia

WHO prequalification: No

Anti-Yamakagashi Antivenom (KM Biologics Co. Ltd, Japan)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1380

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude Yamakagashi venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Below 10°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

In 2000, an equine Yamakagashi (Rhabdophis tigrinus) antivenom was test manufactured by KM Biologics as an unapproved drug for treatment of Yamakagashi bites. The antivenom showed a strong neutralizing ability against the hemorrhagic and coagulation activity of the Yamakagashi venom in its potency test. One vial of the antivenom can effectively neutralize at least about 4 mg of Yamakagashi venom. Its efficacy has also been confirmed in patients with severe cases of R. tigrinus bite that has been used in emergency.Although this antivenom is technically an unapproved drug in Japan, it is extremely valuable for Yamakagashi bite patients. The use of Yamakagashi antivenom in clinical research today is being carried out, even in 2021 due to its social necessity. Thus, within this framework, the Yamakagashi antivenom can be used clinically, with the consent of the patient and the doctor who is treating the patient. For the clinical use of the Yamakagashi antivenom, its quality needs to be confirmed and guaranteed. In 2020, this 20 year old product was tested for potency (anti-coagulant activity), and showed the same potency as those recorded immediately after production. (https://msptm.org/files/Vol38No2/tb-38-2-042-Morokuma-K.pdf)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Inactive

Developers/investigators: KM Biologics Co., Ltd

Preclinical results status: Available

Preclinical sources: https://www.niid.go.jp/niid/JJID/64/397.pdf

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Rhabdophis tigrinus
Snake species *(Sources: other)*	**Rhabdophis subminiatus; Rhabdophis tigrinus**
Snake family	**Colubridae**
Risk category	**Both Category 1 & 2**
Countries	Japan
Regions	East Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Rhabdophis tigrinus	Rhabdophis tigrinus
Snake family		Colubridae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed/available (no clear regulatory approval)

Approval status: Approval status unclear

Approving authority:

Region of use: East Asia

WHO prequalification: No

Bivalent Haemorrhagic Antivenom - HBAV (CDC, Taiwan)

Alternative name(s): Hemato Bivalent Antivenom (HBAV) (against Trimeresurus stejnegeri and Protobothrops mucrosquamatus)

Chemical name: N/A

CAS number: N/A

PCR ID: 1950

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

In Taiwan, the Centers for Disease Control (CDC) produces the Taiwanese Bivalent Haemorrhagic Antivenom against the hemorrhagic venoms of the green habu and the Taiwan habu.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Centre for Disease Control (CDC) Taiwan; National Institute of Preventive Medicine, China

Preclinical results status: Available

Preclinical sources:
https://www.sciencedirect.com/science/article/pii/S0041010121002713https://pubmed.ncbi.nlm.nih.gov/22906718/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Viridovipera stejnegeri; Protobothrops mucrosquamatus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Taiwan
Regions	East Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Trimeresurus popeiorum (Thailand), Trimeresurus vogeli (Vietnam), Trimeresurus gumprechti (Thailand), Trimeresurus macrops (Thailand) and Trimeresurus trigonocephalus (Sri Lanka), Trimeresurus stejnegeri (China and Taiwan), Trimeresurus barati (Indonesia) and Trimeresurus sumatranus (Indonesia) and Trimeresurus albolabris (Thailand)	Viridovipera stejnegeri; Protobothrops mucrosquamatus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Taiwan

Region of use: East Asia

WHO prequalification: No

Bivalent Neurotoxic antivenom - FNAV (CDC, Taiwan)

Alternative name(s): Bivalent antivenom against the neurotoxic venom (FN antivenom) of the Taiwan banded krait (Bungarus multicinctus) and Chinese cobra (Naja atra)

Chemical name: N/A

CAS number: N/A

PCR ID: 1966

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Naja atra and Bungarus multicinctus

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Taiwanese FVAV is a bivalent antivenom — freeze-dried neurotoxic antivenom — against Bungarus multicinctus and Naja atra snake species. Previous studies have shown that FNAV exhibits good clinical effects and is well documented to decrease the rate of death caused by bites from these two snakes, and has more recently been studied for the ability to neutralise the venom of other snakes. (https://www.sciencedirect.com/science/article/pii/S0929664615002430)A 2017 preclinical study evaluated the therapeutic potential of FNAV against the venoms of three Southeast Asian venomous snakes and verified that FNAV neutralizes the lethal effects of N. kaouthia and N. siamensis venom in a mouse model. (https://pubmed.ncbi.nlm.nih.gov/29244815/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Centre for Disease Control (CDC) Taiwan; National Institute of Preventive Medicine, China

Preclinical results status: Available

Preclinical sources: https://pubmed.ncbi.nlm.nih.gov/29244815/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Bungarus multicinctus (Many-banded krait); Naja atra (Chinese cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Taiwan
Regions	East Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus multicinctus; Naja atra; Naja kaouthia; Naja siamensis and Ophiophagus hannah	Bungarus multicinctus; Naja atra; Naja kaouthia; Naja siamensis
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Taiwan

Region of use: East Asia

WHO prequalification: No

Bungarus Antivenom (CDC, Taiwan)

Alternative name(s): Bungarus multicinctus antivenom; Bungarus Antivenom (National Institute of Preventive Medicine, China)

Chemical name: N/A

CAS number: N/A

PCR ID: 1302

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom; Bungarus multicinctus

Route of administration: Intravenous

Ig format: Unknown

Ig final product type/preparation: Unknown

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

No information available.

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Centre for Disease Control (CDC) Taiwan; National Institute of Preventive Medicine, China

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus multicinctus
Snake species *(Sources: other)*	**Bungarus multicinctus (Many-banded krait)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Taiwan
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent immunization, details unclear

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus multicinctus (Many-banded krait)	Bungarus multicinctus (Many-banded krait)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Taiwan; China

Region of use: East Asia

WHO prequalification: No

Bungarus multicinctus antivenom - BmAV (Shanghai Serum Bio-technology Co Ltd, China)

Alternative name(s): +3C; Bungarus multicinctus (Chinese Krait) antivenin

Chemical name: N/A

CAS number: N/A

PCR ID: 1303

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude B. multicinctus venom

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Traditional antivenoms are derived from the plasma/serum of mammals – usually horses – hyperimmunized with selected snake venom(s). The plasma, which contains snake venom-specific immunoglobulins, is then isolated and purified, with immunoglobulins either left intact as whole Ig (IgG) format, or cleaved into F(ab')2 or F(ab) antibody fragments. F(ab')2 fragment antibodies are generated by pepsin digestion of whole IgG antibodies to remove most of the Fc region, leaving some of the hinge region. F(ab')2 fragments have two antigen-binding F(ab) portions linked together by disulfide bonds, so are divalent with a molecular weight of about 110 kDa. (https://www.abcam.com/secondary-antibodies/advantages-of-immunoglobulin-fab-and-fab2-fragments). Most antivenoms are available in liquid or freeze-dried format (to improve stability), and administered intravenously. Although traditional equine plasma derived antivenoms are expensive to develop, labour intensive, and highly immunogenic, often causing severe side effects such as serum sickness or anaphylactic shock, they are nonetheless relatively effective, and currently the only approved therapeutics for snakebite envenoming.B. multicinctus antivenin, produced by Shanghai Serum Bio-technology Company is a monovalent antivenom, against the most dangerous snake species in mainland China. It is comprised of equine immune globulin F(ab´)2 fragments digested by gastric enzymes and provided in a liquid solution (10 ml/vial) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7728252/).https://pubmed.ncbi.nlm.nih.gov/33458998/

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Shanghai Serum Bio-Technology Co

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Bungarus multicinctus
Snake species *(Sources: other)*	**Bungarus multicinctus**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	China
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Bungarus multicinctus; Bungarus fasciatus ; Ophiophagus hannah	Bungarus multicinctus; Ophiophagus hannah
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: China

Region of use: East Asia

WHO prequalification: No

Freeze-dried Habu antivenom (KM Biologics Co. Ltd, Japan)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1377

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude Habu venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 10°C or below

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This product is a lyophilized Habu antivenom produced by collecting and purifying serum from horses immunized with Habu venom and toxoid. It is highly stable thanks to its lyophilized form, and can be stored for up to ten years. It has been approved for use in Japan, where the Habu snake is endemic (https://www.niid.go.jp/niid/en/mrbp-e.html)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: KM Biologics Co., Ltd

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Protobothrops flavoviridis
Snake species *(Sources: other)*	**Protobothrops flavoviridis**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Japan
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Protobothrops flavoviridis	Protobothrops flavoviridis
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA,SRA

Country(ies) where the product is in use: Japan

Region of use: East Asia

WHO prequalification: No

Freeze-dried Mamushi antivenom (KM Biologics Co. Ltd, Japan)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1319

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude Gloydius blomhoffii and Gloydius tsushimaensis venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 10°C or below

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

This product, produced by KM Biologics Co. Japan is a lyophilized Mamushi antivenom produced by collecting and purifying serum from horses immunized with Mamushi venom and toxoid. It is highly stable thanks to its lyophilized form, and can be stored for up to ten years. It has been approved for use in Japan, where the Mamushi snake is found (https://www.niid.go.jp/niid/en/mrbp-e.html). In 2006 a paper was published establishing a standardised regional reference for Mamushi (Gloydius blomhoffii) Antivenom in Japan, Korea and China (https://www.niid.go.jp/niid/images/JJID/59/20.pdf).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: KM Biologics Co., Ltd

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Gloydius blomhoffi; Gloydius tsushimaensis
Snake species *(Sources: other)*	**Gloydius blomhoffii; Gloydius tsushimaensis**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Japan
Regions	East Asia

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Gloydius brevicaudus
Snake species *(Sources: Other)*	Gloydius blomhoffii; Gloydius tsushimaensis	Gloydius brevicaudus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA,SRA

Country(ies) where the product is in use: Japan

Region of use: East Asia

WHO prequalification: No

Kovax Freeze-Dried Agkistrodon (Korean mamushi) Equine Antivenom (KoreaVaccine Co Ltd, Republic of Korea)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1418

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Gloydius brevicaudus venom

Route of administration: Intravenous

Ig format: Intact Ig immunoglobulin molecule (whole)

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Kovax antivenom is the main treatment for toxins produced by the Gloydius species. An injection of Kovax freeze-dried Gloydius brevicaudus antivenom is the primary treatment for snakebites by Gloydius species in Korea. Gloydius is a genus of venomous pit vipers in Asia, formerly called Agkistrodon. The newly named genus Gloydius is very similar to Agkistrodon in North America and has 22 recognized species. Kovax antivenom is the only antivenom used in Korea, and it is necessary to know about its safety and the frequency of adverse reactions to Kovax antivenom. However, research on the epidemiology of adverse reactions is scarce.https://pubmed.ncbi.nlm.nih.gov/32781766/

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Korea Vaccine Co

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Gloydius brevicaudus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	South Korea
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunisation of horses

Effectiveness

Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*	Gloydius brevicaudus; Gloydius intermedius
Snake species *(Sources: Other)*	Gloydius brevicaudus; Gloydius intermedius
Snake family	Viperidae
Risk category	Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: South Korea

Region of use: East Asia

WHO prequalification: No

Monovalent D. acutus antivenom - DaMAV-Taiwan (CDC, Taiwan)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1961

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Deinagkistrodon acutus

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Although cross- neutralization occurs between bivalent antivenom for T. stejnegeri and P. mucrosquamatus and monovalent antivenom for D. acutus, substitution should be avoided as the bivalent antivenom has only a weak cross-reactivity with the D. acutus venom. The Taiwan Poison Control Center thus recommends that 2 to 4 vials of antivenom be administered in a envenomed patient. However, this recommendation was not validated and there is no standard dosing regimen available in Taiwan (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5364662/pdf/40409_2017_Article_111.pdf)https://pubmed.ncbi.nlm.nih.gov/26250942/

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Centre for Disease Control (CDC) Taiwan; National Institute of Preventive Medicine, China

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Deinagkistrodon acutus**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Taiwan
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Immunization of horses

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Deinagkistrodon acutus	Deinagkistrodon acutus
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Not specified

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Taiwan

Region of use: East Asia

WHO prequalification: No

Monovalent Daboia siamensis antivenom - DsMAV-Taiwan (CDC, Taiwan)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1963

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Lyophilized (freeze-dried)

Thermostability: Unknown

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

The monovalent Daboia siamensis antivenom (DsMAV) developed by the Taiwanese Center for Disease Control is comprised of F(ab)'2 immunoglobulin fragments derived from the plasma of horses immunised with the venom of the Siamese Russell's viper (Daboia siamensis). Its efficacy has been shown in both preclinical (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5986800/) and anecdotal clinical studies (https://pubmed.ncbi.nlm.nih.gov/34976069/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Centre for Disease Control (CDC) Taiwan; National Institute of Preventive Medicine, China

Preclinical results status: Available

Preclinical sources: https://www.mdpi.com/2414-6366/3/2/66https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5986800/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Not available
Snake species *(Sources: other)*	**Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper)**
Snake family	**Viperidae**
Risk category	**Both Category 1 & 2**
Countries	Taiwan
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunisation

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper)	Daboia siamensis (Indochinese Russell's viper, Siamese Russell's viper)
Snake family		Viperidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: PLA2s

Syndromic profiles: Haemorrhagic (bleeding),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Taiwan

Region of use: East Asia

WHO prequalification: No

Naja atra monovalent antivenom - NaAV (Shanghai Serum Bio-technology Co Ltd, China)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1353

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment of snakebite envenoming

Target: Crude snake venom: Naja atra (Chinese cobra)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Tha Naja atra antivenom is one of four antivenoms available in China and developed by the Shanghai Serum Bi-technology Company (http://www.serum-china.com.cn/enprodetail/187.html). It is comprised of equine immune globulin F(ab')2 fragments digested by gastric enzymes and provided in liquid solutions (10 ml/vial), and it is capable of neutralising the neurotoxic, cytotoxic and myotoxic effects of systemic Naja atra envenomation as shown by preclinical studies (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7599741/). Oral administration of this antivenom has also been shown to have anti-inflammatory and immunoegulatory actions, which are useful in the treatment of Systemic Lupus Erythematosus (SLE) in preclinical mice studies (https://pubmed.ncbi.nlm.nih.gov/25093033/).

Other indications investigated: Systemic Lupus Erythematosus (SLE)

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Shanghai Serum Bio-Technology Co

Preclinical results status: Available

Preclinical sources:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7599741/https://pubmed.ncbi.nlm.nih.gov/25093033/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Naja atra
Snake species *(Sources: other)*	**Naja atra (Chinese cobra)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	China
Regions	East Asia

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom-dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Not available
Snake species *(Sources: Other)*	Naja atra (Chinese cobra)	Naja atra (Chinese cobra)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Cytotoxic (tissue damage)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: China

Region of use: East Asia

WHO prequalification: No

Australia-Papua (incl Pacific)

Seqirus Black Snake antivenom (Seqirus Pty Ltd, Australia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1378

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Pseudechis australis (King brown snake, mulga snake)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Black snake antivenom is prepared from the plasma of horses immunised with the venom of the king brown snake (Pseudechis australis) also known as the mulga snake. The king brown snake is a member of the genus Pseudechis, known as black snakes. Each vial contains 18,000 units of antivenom which has been standardised to neutralise in vitro the average yield of venom from the king brown snake (https://labeling.seqirus.com/PI/AU/Black-Snake-Antivenom/EN/Black-Snake-Antivenom-Product-Information.pdf). It is light straw coloured, slightly viscous, transparent solution in a glass vial and should be protected from light and stored between 2-8°C (https://labeling.seqirus.com/PI/AU/Black-Snake-Antivenom/EN/Black-Snake-Antivenom-Product-Information.pdf).It was found to be effective in neutralising the PLA2 toxins which is responsible for the anticoagulant (bleeding) and cytotoxic systemic effects of Pseudechis australis, in a preclinical study (https://pubmed.ncbi.nlm.nih.gov/27650695/).Preclinical studies also show its efficacy against the small-eyed snake, Micropechis ikaheka, from Papua New Guinea (https://pubmed.ncbi.nlm.nih.gov/24980637/).(https://pubmed.ncbi.nlm.nih.gov/28764620/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Seqirus Pty Ltd

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/27650695/https://pubmed.ncbi.nlm.nih.gov/27650695/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Pseudechis australis; Pseudechis papuanus; Pseudechis porphyriacus
Snake species *(Sources: other)*	**Pseudechis australis (King brown snake, mulga snake)**
Snake family	**Elapidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	Australia
Regions	Australia-Papua (incl Pacific)

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Pseudechis butleri; Pseudechis colletti; Pseudechis guttatus; Pseudechis rossignolii; Pseudechis weigeli
Snake species *(Sources: Other)*	Pseudechis australis (King brown snake, mulga snake); Pseudechis papuanus (Papuan black snake); Micropechis ikaheka (small-eyed snake)	Pseudechis australis (King brown snake, mulga snake); Micropechis ikaheka (small-eyed snake)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: PLA2s

Syndromic profiles: Haemorrhagic (bleeding),Cytotoxic (tissue damage)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Australia

Region of use: Australia-Papua (incl Pacific)

WHO prequalification: No

Seqirus Brown Snake antivenom (Seqirus Pty Ltd, Australia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1379

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Pseudonaja snakes

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Brown Snake Antivenom is prepared from the plasma of horses immunised with the venom of the eastern brown snake (Pseudonaja textilis). It is indicated for the treatment of patients who exhibit manifestations of systemic envenoming following a bite by a snake of the genus Pseudonaja. This genus includes the eastern brown snake, the dugite and the gwardar (western brown snake). There are no absolute contraindications, but the product should not be used unless there is clear evidence of systemic envenoming with the potential for serious toxic effects. Brown Snake Antivenom should be protected from light and stored at 2-8°C. Do not freeze (https://labeling.seqirus.com/PI/AU/Brown-Snake-Antivenom/EN/Brown-Snake-Antivenom-Product-Information.pdf).Seqirus Brown snake antivenom has also been tested in animal studies in combination with Taipan and Tiger snake AV with neutralisation against a number of Micrurus spp, and partial protection against M. ibiboboca, M. lemniscatus (https://pubmed.ncbi.nlm.nih.gov/27595162/)Preclinical studies also show its efficacy against the small-eyed snake, Micropechis ikaheka, from Papua New Guinea (https://pubmed.ncbi.nlm.nih.gov/24980637/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Seqirus Pty Ltd

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/23300888/https://pubmed.ncbi.nlm.nih.gov/23300888/https://pubmed.ncbi.nlm.nih.gov/23300888/

Evidence of clinical trials? Yes

Phase: N/A, (Status: Unknown, March 2015-): *Randomised controlled trial investigating the effects of early snake antivenom administration* (CT number: ACTRN12615000264583, CT source: https://anzctr.org.au/ACTRN12615000264583.aspx)

Production/source

	Derived from
Snake species *(Source: WHO)*	Pseudonaja textilis
Snake species *(Sources: other)*	**Pseudonaja textilis (Eastern brown snake)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Australia
Regions	Australia-Papua (incl Pacific)

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Pseudonaja affinis; Pseudonaja aspidorhyncha; Pseudonaja guttata; Pseudonaja inframacula; Pseudonaja ingrami; Pseudonaja mengdeni; Pseudonaja nuchalis; Pseudonaja tanneri
Snake species *(Sources: Other)*	Pseudonaja textilis (Eastern brown snake); Pseudonaja affinis (Dugite); Pseudonaja nuchalis (Gwardar or Western brown snake); Micrurus fulvius (Florida coralsnake); Micrurus corallinus (Bocorá, Cobra-coral, Coral-verdadeira, Ibiboboca, Mbói-chumbé, Painted coralsnake, Víbora de coral); Micrurus frontalis, Micrurus nigrocinctus (Babaspul, Central American coralsnake, Coral, Coral centroamericana, Coral macho, Corallilo, Gargantilla, Limlim, Silviara); Micrurus pyrrhocryptus; Micrurus spixii (Acavai, Amazonian coralsnake, Cobra-coral, Coral, Coral venenosa, Coral-verdadeira, Naca-naca, Serpent-corail, Spix's coralsnake); Micrurus altirostris; Micrurus ibiboboca; Micrurus lemniscatus (Bocorá, Cobra-coral, Coral venenosa, Coral-verdadeira, Coralsnake, Hot bead snake, Ibiboboca, Iboboca, Kamung, Kraalsland, Krarasneke, Naca-naca, Serpent-corail, South American coralsnake); Micropechis ikaheka (small-eyed snake)	Pseudonaja textilis (Eastern brown snake); Pseudonaja affinis (Dugite); Pseudonaja nuchalis (Gwardar or Western brown snake); Micropechis ikaheka (small-eyed snake)In combination with Taipan and TIger snake AV: Micrurus fulvius (Florida coralsnake); Micrurus corallinus (Bocorá, Cobra-coral, Coral-verdadeira, Ibiboboca, Mbói-chumbé, Painted coralsnake, Víbora de coral); Micrurus frontalis, Micrurus nigrocinctus (Babaspul, Central American coralsnake, Coral, Coral centroamericana, Coral macho, Corallilo, Gargantilla, Limlim, Silviara); Micrurus pyrrhocryptus; Micrurus spixii (Acavai, Amazonian coralsnake, Cobra-coral, Coral, Coral venenosa, Coral-verdadeira, Naca-naca, Serpent-corail, Spix's coralsnake); Micrurus altirostris; Micrurus ibiboboca (partial); Micrurus lemniscatus (partial) (Bocorá, Cobra-coral, Coral venenosa, Coral-verdadeira, Coralsnake, Hot bead snake, Ibiboboca, Iboboca, Kamung, Kraalsland, Krarasneke, Naca-naca, Serpent-corail, South American coralsnake)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Australia

Region of use: Australia-Papua (incl Pacific)

WHO prequalification: No

Seqirus Death Adder antivenom (Seqirus Pty Ltd, Australia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1389

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Acanthophis antarcticus (Common death adder)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Death Adder Antivenom is prepared from the plasma of horses immunised with the venom of the common death adder (Acanthophis antarcticus). Each vial contains 6,000 units of antivenom which has been standardised to neutralise in vitro the average yield of venom from the death adder (https://labeling.seqirus.com/PI/AU/Death-Adder-Antivenom/EN/Death-Adder-Antivenom-Product-Information.pdf). It is approved for use in Australia by the Australian Register of Therapeutic Goods (ARTG) and should be protected from light and stored at 2-8°C (https://labeling.seqirus.com/PI/AU/Death-Adder-Antivenom/EN/Death-Adder-Antivenom-Product-Information.pdf). It has been found to be effective in neutralising the neurotoxic systemic effects (https://pubmed.ncbi.nlm.nih.gov/28422078/) of snakebite envenomation (https://pubmed.ncbi.nlm.nih.gov/28764620/).

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Seqirus Pty Ltd

Preclinical results status: Unavailable/unknown

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Acanthophis antarcticus
Snake species *(Sources: other)*	**Acanthophis antarcticus (Common death adder)**
Snake family	**Elapidae**
Risk category	**Category 2 (Secondary Medical Importance)**
Countries	Australia
Regions	Australia-Papua (incl Pacific)

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Acanthophis cryptamydros; Acanthophis laevis; Acanthophis praelongus; Acanthophis pyrrhus; Acanthophis rugosus; Acanthophis spp.; Acanthophis wellsi
Snake species *(Sources: Other)*	Acanthophis antarcticus (Common death adder)	Acanthophis antarcticus (Common death adder)
Snake family		Elapidae
Risk category		Category 2 (Secondary Medical Importance)

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Neurotoxic (paralysis)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Australia

Region of use: Australia-Papua (incl Pacific)

WHO prequalification: No

Seqirus Polyvalent antivenom (Seqirus Pty Ltd, Australia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1317

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Pseudechis australis (King brown or mulga snake); Notechis scutatus (Mainland tiger snake); Pseudonaja textilis (Eastern brown snake); Acanthophis antarcticus (Common death adder); Oxyuranus scutellatus (Coastal taipan)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Seqirus polyvalent snake antivenom contains F(ab') antibodies (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228881/) to the venom of the following snakes (https://labeling.seqirus.com/PI/AU/Polyvalent-Snake-Antivenom/EN/Polyvalent-Snake-Antivenom-Product-Information.pdf): Pseudechis australis (King brown or mulga snake); Notechis scutatus (Mainland tiger snake); Pseudonaja textilis (Eastern brown snake); Acanthophis antarcticus (Common death adder); Oxyuranus scutellatus (Coastal taipan). It has been shown to effectively inhibit the PLA2 toxin in the venom of these snakes, which is responsible for their hemorrhagic systemic effects (https://pubmed.ncbi.nlm.nih.gov/27650695/).Seqirus polyvalent snake antivenom is indicated for the treatment of patients in Papua New Guinea and in all Australian states (except Victoria and Tasmania) who exhibit manifestations of systemic snake envenoming and the snake has not been definitely identified. In Tasmania, Tiger Snake Antivenom should be used rather than polyvalent antivenom whilst in Victoria a combination of Tiger Snake Antivenom and Brown Snake Antivenom is the preferred treatment. Seqirus polyvalent snake antivenom should not be used when the snake has been identified, as appropriate monovalent antivenom provides similar neutralisation of the venom without introducing the larger amounts of equine protein present in the polyvalent product (https://labeling.seqirus.com/PI/AU/Polyvalent-Snake-Antivenom/EN/Polyvalent-Snake-Antivenom-Product-Information.pdf). Seqirus polyvalent AV has also been tested against nine Micrurus (coral snake) sp with neutralising effects again all except one - Micrurus spixii (https://pubmed.ncbi.nlm.nih.gov/27595162).Preclinical studies also show its efficacy against the small-eyed snake, Micropechis ikaheka, from Papua New Guinea (https://pubmed.ncbi.nlm.nih.gov/24980637/).This polyvalent antivenom is also officially available in Indonesia (https://pubmed.ncbi.nlm.nih.gov/35296460/)https://pubmed.ncbi.nlm.nih.gov/28764620/

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Preclinical

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Seqirus Pty Ltd

Preclinical results status: Available

Preclinical sources:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228881/https://pubmed.ncbi.nlm.nih.gov/27650695/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228881/

Evidence of clinical trials? Unknown

Production/source

	Derived from
Snake species *(Source: WHO)*	Acanthophis antarcticus; Notechis scutatus; Oxyuranus scutellatus; Pseudechis australis; Pseudechis papuanus; Pseudechis porphyriacus; Pseudonaja textilis
Snake species *(Sources: other)*	**Pseudechis australis (King brown or mulga snake); Notechis scutatus (Mainland tiger snake); Pseudonaja textilis (Eastern brown snake); Acanthophis antarcticus (Common death adder); Oxyuranus scutellatus (Coastal taipan)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Australia; Papua New Guinea
Regions	Australia-Papua (incl Pacific)

Immunizing venom protocol/strategy: Polyspecific (broad spectrum, multi-snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Acanthophis cryptamydros; Acanthophis laevis; Acanthophis praelongus; Acanthophis pyrrhus; Acanthophis rugosus; Acanthophis spp.; Acanthophis wellsi; Austrelaps labialis; Austrelaps ramsayi; Austrelaps superbus; Hoplocephalus bitorquatus; Hoplocephalus bungaroides; Hoplocephalus stephensii; Micropechis ikaheka; Oxyuranus microlepidotus; Oxyuranus temporalis; Pseudechis butleri; Pseudechis colletti; Pseudechis guttatus; Pseudechis rossignolii; Pseudechis weigeli; Pseudonaja affinis; Pseudonaja aspidorhyncha; Pseudonaja guttata
Snake species *(Sources: Other)*	Pseudechis australis (King brown or mulga snake); Notechis scutatus (Mainland tiger snake); Pseudonaja textilis (Eastern brown snake); Acanthophis antarcticus (Common death adder); Oxyuranus scutellatus (Coastal taipan); Micrurus corallinus (Bocorá, Cobra-coral, Coral-verdadeira, Ibiboboca, Mbói-chumbé, Painted coralsnake, Víbora de coral); Micrurus fulvius (Eastern coralsnake, Florida coralsnake, Harlequin coralsnake); Micrurus nigrocinctus (Babaspul, Central American coralsnake, Coral, Coral centroamericana, Coral macho, Corallilo, Gargantilla, Limlim, Silviara); Micrurus spixii (Acavai, Amazonian coralsnake, Cobra-coral, Coral, Coral venenosa, Coral-verdadeira, Naca-naca, Serpent-corail, Spix's coralsnake); Micropechis ikaheka (small-eyed snake)	Pseudechis australis (King brown or mulga snake); Notechis scutatus (Mainland tiger snake); Pseudonaja textilis (Eastern brown snake); Acanthophis antarcticus (Common death adder); Oxyuranus scutellatus (Coastal taipan); Micrurus corallinus (Bocorá, Cobra-coral, Coral-verdadeira, Ibiboboca, Mbói-chumbé, Painted coralsnake, Víbora de coral); Micrurus fulvius (Eastern coralsnake, Florida coralsnake, Harlequin coralsnake); Micrurus nigrocinctus (Babaspul, Central American coralsnake, Coral, Coral centroamericana, Coral macho, Corallilo, Gargantilla, Limlim, Silviara); Micropechis ikaheka (small-eyed snake)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: PLA2s

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Indonesia; Australia

Region of use: Australia-Papua (incl Pacific)

WHO prequalification: No

Seqirus Taipan antivenom (Seqirus Pty Ltd, Australia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1375

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Oxyuranus scutellatus (Coastal Taipan, Papuan taipan)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Seqirus Taipan antivenom is prepared from the plasma of horses immunised with the venom of the coastal taipan snake (Oxyuranus scutellatus). Each vial contains 12,000 units of antivenom which has been standardised to neutralise in vitro, the average yield of venom from the taipan. It is a light straw coloured, slightly viscous, transparent solution in a glass vial. It is indicated for the treatment of patients who exhibit manifestations of systemic envenoming following a bite by a taipan (https://labeling.seqirus.com/PI/AU/Taipan-Antivenom/EN/Taipan-Antivenom-Product-Information.pdf).Seqirus Taipan antivenom has also been tested in animal studies against in combination with Brown and Tiger snake AV with neutralisation against a number of Micrurus spp, and partial protection against Micrurus ibiboboca, Micrurus lemniscatus (https://pubmed.ncbi.nlm.nih.gov/27595162/). It has been found to be effective in neutralising neurotoxicity caused by systemic Taipan envenomation, particularly the PLA2 toxins within the Taipan venom, by multiple preclinical reports (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7694127/) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4113736/) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228881/) (https://pubmed.ncbi.nlm.nih.gov/27903075/).https://pubmed.ncbi.nlm.nih.gov/28764620/

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Seqirus Pty Ltd

Preclinical results status: Available

Preclinical sources:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7694127/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7694127/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4113736/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4228881/

Evidence of clinical trials? Yes

Phase I/Phase II, (Status: Active, October 2012-): *A Phase I/Phase II randomized controlled trial (RCT) of a new antivenom, compared to the currently used CSL taipan antivenom, for the treatment of the effects of Papuan taipan bite* (CT number: ACTRN12612001062819, CT source: https://anzctr.org.au/ACTRN12612001062819.aspx)

Production/source

	Derived from
Snake species *(Source: WHO)*	Oxyuranus scutellatus
Snake species *(Sources: other)*	**Oxyuranus scutellatus (Coastal Taipan, Papuan taipan)**
Snake family	**Elapidae**
Risk category	**Both Category 1 & 2**
Countries	Australia
Regions	Australia-Papua (incl Pacific)

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Oxyuranus microlepidotus; Oxyuranus temporalis
Snake species *(Sources: Other)*	Oxyuranus scutellatus (Coastal Taipan, Papuan taipan); Oxyuranus temporalis (Western ranges taipan); Oxyuranus microlepidotus (Fierce snake, Inland taipan, Small-scaled snake); Micrurus fulvius (Florida coralsnake); Micrurus corallinus (Bocorá, Cobra-coral, Coral-verdadeira, Ibiboboca, Mbói-chumbé, Painted coralsnake, Víbora de coral), Micrurus frontalis, Micrurus nigrocinctus (Babaspul, Central American coralsnake, Coral, Coral centroamericana, Coral macho, Corallilo, Gargantilla, Limlim, Silviara); Micrurus pyrrhocryptus; Micrurus spixii (Acavai, Amazonian coralsnake, Cobra-coral, Coral, Coral venenosa, Coral-verdadeira, Naca-naca, Serpent-corail, Spix's coralsnake); Micrurus altirostris; Micrurus ibiboboca; Micrurus lemniscatus (Bocorá, Cobra-coral, Coral venenosa, Coral-verdadeira, Coralsnake, Hot bead snake, Ibiboboca, Iboboca, Kamung, Kraalsland, Krarasneke, Naca-naca, Serpent-corail, South American coralsnake)	Oxyuranus scutellatus (Coastal Taipan, Papuan taipan); Oxyuranus temporalis (Western ranges taipan); Oxyuranus microlepidotus (Fierce snake, Inland taipan, Small-scaled snake)In combination with Brown and TIger snake AV: M. fulvius (Florida coralsnake); Micrurus corallinus (Bocorá, Cobra-coral, Coral-verdadeira, Ibiboboca, Mbói-chumbé, Painted coralsnake, Víbora de coral), Micrurus frontalis, Micrurus nigrocinctus (Babaspul, Central American coralsnake, Coral, Coral centroamericana, Coral macho, Corallilo, Gargantilla, Limlim, Silviara); Micrurus pyrrhocryptus; Micrurus spixii (Acavai, Amazonian coralsnake, Cobra-coral, Coral, Coral venenosa, Coral-verdadeira, Naca-naca, Serpent-corail, Spix's coralsnake); Micrurus altirostris; Micrurus ibiboboca (partial); Micrurus lemniscatus (partial) (Bocorá, Cobra-coral, Coral venenosa, Coral-verdadeira, Coralsnake, Hot bead snake, Ibiboboca, Iboboca, Kamung, Kraalsland, Krarasneke, Naca-naca, Serpent-corail, South American coralsnake)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: PLA2s

Syndromic profiles: Neurotoxic (paralysis),Haemorrhagic (bleeding)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA,SRA

Country(ies) where the product is in use: Australia

Region of use: Australia-Papua (incl Pacific)

WHO prequalification: No

Seqirus Tiger Snake antivenom (Seqirus Pty Ltd, Australia)

Alternative name(s): N/A

Chemical name: N/A

CAS number: N/A

PCR ID: 1316

Include in data set: Yes

Technical profile

Biologics > Immunoglobulin products - animal plasma/serum derived

New chemical or biological entity

Indication: Treatment for snakebite envenoming

Target: Crude snake venom; Notechis scutatus (tiger snake); Austrelaps (copperhead snakes); Pseudechis (black snakes)

Route of administration: Intravenous

Ig format: F(ab')2 immunoglobulin molecule fragments

Ig final product type/preparation: Liquid final product

Thermostability: 2-8°C

Mechanism of action: Antibodies or antibody fragments derived from the plasma of immunized animals bind specific components/toxins (antigens) within snake venom to neutralize its effects.

MeSH headings / pharmacological class: Antibodies; immunological factors; antivenin; antidotes

Key features and challenges:

Tiger snake antivenom is prepared from the plasma of horses immunised with the venom of the mainland tiger snake (Notechis scutatus) and is produced in liquid form. Seqirus' Tiger snake antivenom is indicated for the treatment of patients who exhibit manifestations of systemic envenoming following a bite by a tiger, copperhead or black snake, further product details can be found at https://labeling.seqirus.com/PI/AU/Tiger-Snake-Antivenom/EN/Tiger-Snake-Antivenom-Product-Information.pdf.Seqirus Tiger Snake antivenom has also been tested in animal studies against Micrurus fulvius (Florida coralsnake) with demonstrated neutralization effects. (https://pubmed.ncbi.nlm.nih.gov/12645961/). It has also been tested in combination with Brown and Taipan snake AV with partial protection against M. lemniscatus (https://pubmed.ncbi.nlm.nih.gov/27595162/). It has also been demonstrated in vitro to neutralize the inhibition of twitches of the chick biventer cervicis nerve-muscle preparation caused by Naja haje (Egyptian cobra) venom (https://pubmed.ncbi.nlm.nih.gov/22788931/). It has been found to be effective in the treatment of procoagulant and cytotoxic systemic effects of envenomation (https://pubmed.ncbi.nlm.nih.gov/33017183/). Clinical trials include ACTRN12611000588998 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4565558/)Preclinical studies also show its efficacy against the small-eyed snake, Micropechis ikaheka, from Papua New Guinea (https://pubmed.ncbi.nlm.nih.gov/24980637/)

Other indications investigated: N/A

Development lifecycle

Marketed snakebite product

Current R&D stage (SBE): Post-marketing human safety/efficacy studies (without prior clinical studies)

Highest R&D stage (any condition): Marketed (SBE)

Development status: Active

Developers/investigators: Seqirus Pty Ltd

Preclinical results status: Available

Preclinical sources:
https://pubmed.ncbi.nlm.nih.gov/22860796/https://pubmed.ncbi.nlm.nih.gov/22860796/

Evidence of clinical trials? Yes

Phase: N/A, (Status: Unknown, March 2015-): *Randomised controlled trial investigating the effects of early snake antivenom administration* (CT number: ACTRN12615000264583, CT source: https://anzctr.org.au/ACTRN12615000264583.aspx)

Phase III/Phase IV, (Status: Active, June 2011-): *A randomised controlled trial of antivenom for red-bellied black snake envenoming* (CT number: ACTRN12611000588998, CT source: https://anzctr.org.au/ACTRN12611000588998.aspx)

Production/source

	Derived from
Snake species *(Source: WHO)*	Notechis scutatus
Snake species *(Sources: other)*	**Notechis scutatus (Mainland tiger snake)**
Snake family	**Elapidae**
Risk category	**Category 1 (Highest Medical Importance)**
Countries	Australia
Regions	Australia-Papua (incl Pacific)

Immunizing venom protocol/strategy: Monospecific (single snake venom specificity)

Production technique and/or immunization strategy: Venom dependent equine immunization

Effectiveness

	Tested in	Effective against (any efficacy data)
Snake species *(Source: WHO)*		Austrelaps labialis; Austrelaps ramsayi; Austrelaps superbus; Hoplocephalus bitorquatus; Hoplocephalus bungaroides; Hoplocephalus stephensii; Pseudechis butleri; Pseudechis colletti; Pseudechis guttatus; Pseudechis porphyriacus; Pseudechis weigeli; Tropidechis carinatus
Snake species *(Sources: Other)*	Notechis scutatus (tiger snake); Austrelaps (copperhead snakes); Pseudechis (black snakes); Micrurus fulvius (Florida coralsnake); Micrurus corallinus (Bocorá, Cobra-coral, Coral-verdadeira, Ibiboboca, Mbói-chumbé, Painted coralsnake, Víbora de coral), Micrurus frontalis, Micrurus nigrocinctus (Babaspul, Central American coralsnake, Coral, Coral centroamericana, Coral macho, Corallilo, Gargantilla, Limlim, Silviara); Micrurus pyrrhocryptus; Micrurus spixii (Acavai, Amazonian coralsnake, Cobra-coral, Coral, Coral venenosa, Coral-verdadeira, Naca-naca, Serpent-corail, Spix's coralsnake); Micrurus altirostris; Micrurus ibiboboca; Micrurus lemniscatus (Bocorá, Cobra-coral, Coral venenosa, Coral-verdadeira, Coralsnake, Hot bead snake, Ibiboboca, Iboboca, Kamung, Kraalsland, Krarasneke, Naca-naca, Serpent-corail, South American coralsnake); Naja naja (Indian cobra, Spectacled cobra); Micropechis ikaheka (small-eyed snake)	Notechis scutatus (tiger snake); Austrelaps (copperhead snakes); Pseudechis (black snakes); Micrurus fulvius (Florida coralsnake); Micrurus lemniscatus (Bocorá, Cobra-coral, Coral venenosa, Coral-verdadeira, Coralsnake, Hot bead snake, Ibiboboca, Iboboca, Kamung, Kraalsland, Krarasneke, Naca-naca, Serpent-corail, South American coralsnake); Naja naja (Indian cobra, Spectacled cobra); Micropechis ikaheka (small-eyed snake)
Snake family		Elapidae
Risk category		Both Category 1 & 2

Direct action on toxins? Yes

Target toxin class: Both high and low toxicity toxins

Specific target toxin class: N/A

Syndromic profiles: Cytotoxic (tissue damage),Procoagulant (blood clotting)

Registration details

Clinical use status: Marketed (regulatory approval)

Approval status: Approved

Approving authority: NRA

Country(ies) where the product is in use: Australia

Region of use: Australia-Papua (incl Pacific)

WHO prequalification: No