Snake Venom Antiserum I.P.

स्नेक वेनम् ऐन्टीसिरम आई.पी.

50 mL

For IV infusion use only

(Lyophilized)

For sale in India only

BSV

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.
READ PACKAGE INSERT CAREFULLY BEFORE USE
PRESCRIBING INFORMATION.

Snake Venom Antiserum I.P.

(50 mL Vial)

For I.V. Infusion Use only

(Lyophilized)

1. Generic Name:
Snake Venom Antiserum I.P.

2. Qualitative and Quantitative Composition:
After reconstitution Each mL Neutralizes the following quantities of standard venoms of:

Cobra	0.6 mg
Common Krait	0.45 mg
Russell's Viper	0.6 mg
Saw-scaled Viper	0.45 mg

Preservative: Cresol I.P. NMT 0.25% v/v
Stabilizer: Glycine I.P.
Excipients: Mannitol I.P. and Sodium Chloride I.P.
Reconstitute the content of each vial with 50 mL of Sterile Water for Injection I.P.

3. Dosage form:
Lyophilized Powder for Injection.

4. Clinical particulars:
4.1. Therapeutic Indication:
Snake Venom Antiserum is indicated for the treatment of envenomation caused by bites of the snakes as specified below:
• Cobra,
• Common Krait.
• Russell's Viper.
• Saw-scaled Viper.

4.2. Posology and method of administration:
Method of Administration:
The patient should receive the antivenom in an intensive care unit if possible and always in a setting where resuscitation facilities are immediately available.
Reconstitute each vial of Lyophilized Snake Venom Antiserum with 50 mL of Sterile Water for Injection provided with this pack. After adding the diluent, shake the vial gently to dissolve the contents.
OR
Snake Venom Antiserum is administered intravenously either undiluted at the rate of not more than 1 mL per minute or is diluted in 500 mL of intravenous fluid (either Sodium Chloride solution or 5% Dextrose solution) and administered as rapidly as tolerated over 1-2 hours. While diluting the Snake Venom Antiserum, mix by continuous manual inversion and gentle swirling until no solid matter is visible in the vial. Do not shake and avoid foaming.
The aim of the antivenom therapy is to neutralize the venom. Sufficient antivenom must be given to neutralize further venom migrating from the snake bite location(s) on body. Deterioration in the patient's condition may indicate that treatment is inadequate, and more vials may be required. In such a case, additional infusions should be repeated hourly until progressive swelling in the bitten part ceases and systemic signs and symptoms disappear such as seen in cases of coagulopathy. When an adequate dosage is achieved, the improvement in patient's clinical signs is often seen.

Anti-Snake venom (ASV) dose : (Government of India Guidelines as NAPSE) (Refer Ref no.1)
Dose of ASV for neuroparalytic snakebite – ASV 100 mL stat as infusion over 30 minutes followed by 2nd dose of 100 mL after 1 hour if no improvement within 1st hour.
Adult: Neuroparalytic snake bite: First dose 10 vials of ASV as infusion for over 30 to 90 minutes followed by a 2nd dose of 100 vials (2 Vials of 50 mL) after 1 hour (only if no improvement seen within the 1st hour). Repeated dose
Repeat ASV when there is worsening neurotoxic or cardiovascular signs even after 1–2 hr.

Maximum dose of 200 mL (4 Vials of 50 mL) ASV vials can be given for neurotoxically envenomed patients. If large doses have been administered and the coagulation abnormality persists, give fresh frozen plasma (FFP) or cryoprecipitate (fibrinogen, factor VIII), fresh whole blood, if FFP not available or platelet concentrate.

Vasculotoxic snake bite First dose 100 mL (2 Vials of 50 mL) of polyvalent ASV stat over 30 to 90 minutes as infusion, followed by 6 vials 6 hourly as bolus therapy till clotting time normalizes and/or local swelling subsides.
Repeated dose:
Repeat clotting test every 6 hours until coagulation is restored. Administer ASV every 6 h until coagulation is restored. If 300 mL (6 Vials of 50 mL) of ASV have been administered reconsider whether continued administration of ASV is serving any purpose, particularly in the absence of proven systemic bleeding.

Pregnancy: Pregnant women are treated in exactly the same way as other victims. The same dosage of ASV should be given. However, the change in the physiology in pregnancy should be monitored. Refer the victim to a gynaecologist for assessment of any impact on the foetus.

Children: Children are also given exactly the same dose of ASV as adults, as snakes inject the same amount of venom into children and adults. Infusion: liquid or reconstituted ASV is diluted in 5-10 mL/kg body weight of normal saline. However, reduce the amount of fluid in the running bottle to 200 mL to avoid fluid overload.
Dose of ASV for vasculotoxic snakebite – Two regimens low dose infusion therapy and high

dose intermittent bolus therapy can be used. Low dose infusion therapy is as effective as high dose intermittent bolus therapy and also saves scarce ASV doses (Expert Consensus). Reference;Management of Snake Bite,Full Background Document (Draft),January 2016
Low Dose infusion therapy – ASV 100 mL (2 Vials of 50 mL) for Russel's viper or 60 mL for Saw scaled viper as stat in the form of infusion over 30 minutes followed by 20 mL ASV every 6 hours as infusion in 100 mL of normal saline till clotting time normalizes or for 3 days whichever is earlier.
OR
High dose intermittent bolus therapy - 100 mL (2 Vials of 50 mL) of polyvalent ASV stat over 30 minutes as infusion, followed by 60 mL of polyvalent ASV 6 hourly as bolus therapy till clotting time normalizes and/or local swelling subsides.

The range of venom injected is 5 mg-147 mg. The total required dose range is between 100 mL to 300 mL of polyvalent ASV, as each mL of polyvalent ASV neutralizes 0.6 mg of Russell's Viper venom. Depending on the patient condition, additional dose can be considered. No ASV for Sea snakebite, confirmed Green Pit snakebite even if with signs of envenomation as available ASV do not contain antibodies against them.
IT IS NOT ADVISABLE / RECOMMENDED TO INJECT SNAKE VENOM ANTISERUM AT THE LOCAL SITE OF BITE.

4.3. Contraindications
There are no absolute contraindications to ASV. However, do not routinely administer ASV to any patient claiming to have been bitten by a snake as ASV exposes such patients to the risks of ASV reactions unnecessarily; besides wastage of valuable and scarce stocks of ASV. However, at the same time one should not delay or withhold ASV on the grounds of anaphylactic reaction to a deserving patient. Do NOT give incomplete dose.

4.4. Special warnings and precautions for use:
Precautions:
Product should not be used unless there is clear evidence of systemic envenoming with the potential for serious toxic effects.
To check the clarity of the reconstituted solution before its administration. Before administration of reconstituted solution of Snake Venom Antiserum, appropriate measures must be taken in an effort to detect the presence of dangerous sensitivity such as any other product prepared from horse serum.
A careful review of the patient's history is required to be made for any report or history of asthma, urticaria or other allergic manifestations including allergic reactions upon exposure to horses or prior injections of horse serum based products.
Although results of skin test to determine patients who may have an allergic reaction are not satisfactory, it may be performed prior to administration regardless of the clinical history.
SKIN TEST:
Inject intradermally 0.02 to 0.03mL of a 1:10 dilution of Snake Venom Antiserum. A control test on the opposite extremity using Sodium Chloride Injection facilitates easy interpretation. A positive reaction to a skin test occurs within 5 to 30 minutes. The shorter the interval between injection and the beginning of the skin reaction, the greater is the sensitivity. If the allergic history is negative and the result of the skin test is negative, proceed with administration of Snake Venom Antiserum.
If the allergic history is positive and the skin test is strongly positive, administration may be dangerous, especially if the positive sensitivity test is accompanied by systemic allergic manifestations. In such cases, the risk of administering Snake Venom Antiserum must be weighed against the risk of withholding it, keeping in mind that severe envenomation can be fatal.
If the history is negative and the skin test is mildly positive administer as follows:
Prepare in separate sterile syringes 1:100 and 1:10 dilutions of Snake Venom Antiserum. Inject subcutaneously using a tuberculin type syringe, 0.1, 0.2 and 0.5mL of the 1:100 dilution at 15 minutes intervals, repeat with 1:10 dilutions and finally undiluted Snake Venom Antiserum.
If a systemic reaction occurs after any injection, place a tourniquet proximal to the site of injection and administer an appropriate dose of Epinephrine 1:1000, proximal to the tourniquet or into another extremity. Wait for at least 30 minutes before injecting another dose. If no reaction occurs after 0.5mL of undiluted Anti Snake Venom Serum has been administered, switch over to the intramuscular route and continue doubling the dose at 15 minutes intervals until the entire dose has been injected intramuscularly.
Wingert and Wainschel have described a procedure based on the experience of their group which they have used in some severely envenomated patients who have positive sensitivity tests. 50 to 100mg of diphenhydramine hydrochloride is given intravenously followed by slow intravenous infusion of diluted Snake Venom Antiserum for 15 to 20 minutes while carefully observing the patient for symptoms and signs of anaphylaxis. If anaphylaxis does not occur, Snake Venom Antiserum is continued maintaining close observation of the patient. Patients who require Snake Venom Antiserum but develop signs of impending anaphylaxis in spite of this or the procedure described earlier present difficult problem, consultation should be sought.

Routine Product should not be used unless there is clear evidence of systemic envenoming with the potential for serious toxic effects.use of prophylactic adrenaline is recommended before ASV, except in known person with hypertension, and if patient presents with blood pressure more than 140/90 in adult victims or if there is evidence or suspicion of underlying cardiovascular disease. The adult dose of adrenaline (epinephrine) is 0.25 mg of 0.1% solution by subcutaneous injection (For children it is 0.005 mg/kg bodyweight of 0.1% solution). Use of histamine, anti-H1 and anti-H2 blockers, corticosteroids and the rate of intravenous infusion of antivenom between 10 and 120 minutes do not affect the incidence or severity of early antivenom reactions. Skin or Conjunctival Test for has been discarded in the WHO,SEARO,Guideline 2010.

4.5. Drug interactions:
There are no known drug interactions, and no information is available from any published article or report.

For high risk patients :As per WHO Guidelines
In patients with history of hypersensitivity or exposure to animal serum such as equine ASV, tetanusimmune globulin or rabies-immune globulin in past, severe atopic conditions:
1. Give ASV only if they have signs of systemic envenoming.
2. Give Inj. Hydrocortisone 200 mg and Chlorpheniramine maleate 22.75 mg prior to the administration of ASV.

4.6. Use in special populations:
ASV dose in pregnancy and lactation:
ASV should be given in same dose and same criteria as standard victims (STANDARD TREATMENT GUIDELINES Management of Snake Bite;Full Background Document (Draft)'January 2016).

There is limited but inconclusive information on the safety of the product in pregnant women. It is advisable to carefully weigh the risks of untreated envenoming against the expected benefits and potential risks of antivenom administration. Envenomed pregnant women are at risk of fetal distress, premature labour, ante and post partum bleeding and stillbirth. Antivenom treatment is indicated as it outweighs the risks of anaphylaxis. In case of severe anaphylaxis, epinephrine can be administered at the doctors discretion. Pregnant women are treated in exactly the same manner as other victims of snake bite. The same dosage of ASV is given. Refer the victim to a gynecologist for assessment of any impact on the foetus as cross placental transmission of the venoms is possible. No information is available on the use of the product during lactation. It is advisable to carefully weigh the risks of untreated envenoming against the expected benefits and potential risks of antivenom administration.

ASV dose in children:
ASV should be given in same dose and same criteria as standard victims (STANDARD TREATMENT GUIDELINES Management of Snake Bite;Full Background Document (Draft)'January 2016).
Children also are given exactly the same dose of ASV as adults as snakes inject the same amount of venom into children as well as adults. Infusion: liquid or reconstituted ASV is diluted in 5-10mL/kg body weight of normal saline. However, reduce amount of fluid in running bottle to 200 mL to avoid fluid overload.

ASV dosage in victims requiring life-saving surgery:
Rarely patient may develop intracranial bleeding for which a life-saving surgery is required. In such cases, before surgery, coagulation must be restored to avoid catastrophic bleeding and higher initial dose of ASV (up to 300 mL) can be administered.

4.7. Effects on ability to drive and use machines:
Not applicable, as generally in-patients or patients admitted in Hospital receive this injection.

4.8.Undesirable effects:
Injection of heterologous animal proteins can cause severe acute and delayed hypersensitivity reactions and a possible febrile response to immune complexes formed by animal antibodies and neutralized venom components. Antivenoms may bind to complement and product anaphylactoid reactions in patients who have had previous contact with equine proteins. This risk can be reduced by adequate dilution of the antivenom prior to infusion, although care should be taken to avoid circulatory overload.
Systemic Reactions:
The immediate reaction (shock & anaphylaxis) usually occurs within 30 minutes. Symptoms and signs may develop before the needle is withdrawn and include urticaria, edema of the face, tongue and throat, cough, dyspnea, cyanosis, vomiting and collapse.
Serum sickness usually occurs 5 to 24 days after administration. The incubation period may be less than 5 days in those who have received preparations containing horse serum in the past. The usual symptoms and signs are pyrexia, chills, urticaria, edema, diarrhea, nausea and vomiting. Occasionally neurological manifestations, myalgia and muscle weakness may also be seen.

4.9. Overdose:
If large doses have been administered and the coagulation abnormality persists, give fresh frozen plasma (FFP) or cryoprecipitate (fibrinogen, factor VIII), or give fresh whole blood, if both FFP and cryoprecipitate are not available.

5. Pharmacological properties:
5.1. Mechanism of Action:
The venoms of snakes from India contain neurotoxins which can cause respiratory paralysis and coagulants causing hematological complications. Snake Venom Antiserum (Polyvalent) Lyophilized is a venom-specific F(ab')2 fragment of immunoglobulin G (IgG) and works by binding and neutralizing the venom toxins, facilitating their distribution away from target tissues and their elimination from the body.

5.2. Pharmacodynamic properties:
Bivalent antibodies such as F(ab')2 fragments being large molecules have a shorter half-life, reduced immunogenicity leading to fewer adverse reactions, and potentially better tissue penetration remain in circulation for a longer time. Thus, they are not only effective against the small molecular weight neurotoxins but also help in complete and prolonged neutralization of circulating intravascular toxins such as the pre-coagulant enzymes.

5.3. Pharmacokinetic properties:
The antivenom will eventually be released in the body. No specific information is available on absorption, distribution, metabolism or excretion of antivenoms.

6. Nonclinical properties
6.1. Animal Toxicology or Pharmacology:
The antivenom is effective in neutralizing the venoms of BIG 4 (Cobra, Common Krait, Russell's Viper, Saw-scaled Viper) clinically important Indian snakes in a murine lethality model. The product may possess antigenic cross-reactivity against the venoms of some closely related species, however there is no clinical evidence to confirm these findings.

7. Description:
Snake Venom Antiserum (Polyvalent) Lyophilized is a refined and concentrated preparation of Equine serum globulins (Polyvalent Immune Fab'2 fragments) obtained by fractionating plasma from healthy hyperimmunized horses who have passed viral screening tests. All animals are subjected to medical examinations, laboratory tests and a review of the medical history before being allowed to donate plasma for the manufacture of antivenoms.
Snake Venom Antiserum is a cream to pale yellow powder or cake which on reconstitution yields a clear, colourless or pale yellow colored liquid.

8. Pharmaceutical particulars:
8.1. Incompatibilities:
Incompatibilities have not been assessed or identified.

8.2. Shelf-life:
Please refer Carton for details.

8.3. Packaging information
Snake Venom Antiserum I.P. Lyophilized is supplied in 50 mL vial along with 50 mL Sterile Water for Injection I.P.
Kindly note, Snake Venom Antiserum I.P. is available in two presentations in the market i.e., 10 mL Vial & 50 mL Vial.

8.**4. Storage and handling instructions:**
Store in a cool & dark place. Do not freeze. Avoid exposure to excessive heat.

9. Patient Counselling Information:
9.1. What does this package leaflet contain?
Snake bite may cause severe tissue damage, brain and nerves toxicity, bleeding or fatal envenomation. The physician responsible for treatment of the envenomated patients should be familiar with the contents of this pack insert and the medical literature concerning current concepts of first aid and general supportive therapy with respect to administration and treatment of envenomed patients.

9.2. What is Snake Venom Antiserum?
Snake Venom Antiserum (Polyvalent) Lyophilized is an equine-derived antivenom indicated for the management of adult and pediatric patients. It is a refined and concentrated preparation of Equine serum globulins (Polyvalent Immune Fab'2 fragments) obtained by fractionating plasma from healthy hyperimmunized horses who have passed viral screening tests.

9.3. Which case this medicine should be used?
Snake Venom Antiserum is indicated for the treatment of envenomation caused by bites of the snakes as specified, Cobra (Naja naja), Common Krait (Bungarus caeruleus), Russell's Viper (Vipera russelli), Saw-scaled Viper (Echis carinatus).

9.4. Which information you must know before taking Snake Venom Antiserum?
To check the clarity of the reconstituted solution before administration. Before administration of reconstituted solution of Snake Venom Antiserum appropriate measures must be taken to detect the presence of dangerous sensitivity like any other product prepared from horse serum. A careful review of the patient's history is required to be made for any report of asthma, urticaria or other allergic manifestations including allergic reactions upon exposure to horses or prior injections of horse serum. A suitable test for detection of sensitivity (Skin test) may be performed in every patient prior to administration regardless of clinical history.

9.5. You must not be given / Care should be taken:
There are no absolute contraindications to Anti Snake Venom (ASV). However, do not routinely administer ASV to any patient claiming to have been bitten by a snake as ASV exposes such patients to the risks of ASV reactions unnecessarily, besides wastage of valuable and scarce stocks of ASV. However, at the same time do not delay or withhold ASV on the grounds of anaphylactic reaction to a deserving case. Do NOT give an incomplete dose.

9.6. How to take Snake Venom Antiserum? Instruction for good use:
ASV should be administered only by the IV route, and slowly, with the physician at the bed side during the initial period to intervene immediately at the first sign of any reaction. Observe all patients carefully every 5 min for first 30 min, then at 15 min for 2 hours for manifestation of a reaction. At the earliest sign of an adverse reaction suspend the administration temporarily. The rate of infusion can be increased gradually in the absence of a reaction until the full starting dose has been administered (over a period of ~1 hour).

9.7. Warnings and precautions:
Reconstitute Snake Venom Antiserum supplied in dry powder form by diluting in 50 mL of Sterile Water for Injections. Mixing is done by swirling and not by vigorous shaking. Caution: Do not use, if reconstituted solution is opaque to any extent. Give prophylactic epinephrine 0.25 mg of 0.1% solution by subcutaneous injection (Children 0.005 mg/kg body weight of 0.1% solution) except in known hypertensive or patients with cardiovascular disease and draw Epinephrine (adrenaline) in readiness in two syringes before Snake Venom Antiserum is administered.

- NEVER give Snake Venom Antiserum by IM route and do NOT inject the Snake Venom Antiserum locally at the bite site.
- Take all aseptic precautions before starting Snake Venom Antiserum to prevent any pyrogenic reactions to Snake Venom Antiserum. Maintain a strict intake output chart and note colour of urine to detect acute kidney injury early.

9.8. What are the possible side effects?
The immediate reaction (shock & anaphylaxis) usually occurs within 30 minutes. Symptoms and signs may develop before the needle is withdrawn and include urticaria, edema of the face, tongue and throat, cough, dyspnea, cyanosis, vomiting and collapse. Serum sickness usually occurs 5 to 24 days after administration. The incubation period may be less than 5 days in those who have received preparations containing horse serum in the past. The usual symptoms and signs are fever, urticaria, edema, nausea and vomiting. Occasionally neurological manifestations develop. Pain and muscle weakness are frequently present.

9.9. Reporting of side effects:
To report suspected adverse reaction, contact Bharat Serums and Vaccines Ltd. by e-mail at pv@bsvgroup.com or visit the website https://www.bsvgroup.com/adverse/

9.10. How are you given Snake Venom Antiserum:
Snake Venom Antiserum is administered intravenously either undiluted at the rate of not more than 1 mL per minute or is diluted in 500 mL of intravenous fluid (either Sodium Chloride Injection or 5% Dextrose Injection) and administered as rapidly as tolerated over 1-2 hours. While diluting the Snake Venom Antiserum, mix by gentle swirling rather than shaking to avoid foaming.

9.11. If you are given more Snake Venom Antiserum than you should have been given:
If large doses have been administered and the coagulation abnormality persists, give fresh frozen plasma (FFP) or cryoprecipitate (fibrinogen, factor VIII), or give fresh whole blood, if both FFP and cryoprecipitate are not available.

9.12. How to store?
Store in a cool & dark place. Do not freeze. Avoid exposure to excessive heat.

9.13. Contents of the pack and other information:
Snake Venom Antiserum I.P. Lyophilized is supplied in 50 mL vial along with one 50 mL ampoule of Sterile Water for Injection I.P.
Kindly note, Snake Venom Antiserum I.P. is available in two presentations in the market i.e., 10 mL Vial & 50 mL Vial.
On reconstitution with Sterile Water for Injection as recommended, each ml of the Snake Venom Antiserum neutralizes the following quantities of standard venoms.

Cobra	0.6 mg
Common Krait	0.45 mg
Russell's Viper	0.6 mg
Saw-scaled Viper	0.45 mg

Preservative: Cresol I.P. NMT 0.25% v/v
Stabilizer: Glycine I.P.
The other ingredients are Mannitol I.P. and Sodium Chloride I.P.

9.14. What Snake Venom Antiserum I.P. Lyophilized looks like and contents of the pack:
1 glass vial contains cream to pale yellow powder or cake of Snake Venom Antiserum I.P. in a carton along with one 50 mL vial of Sterile Water for Injection I.P.

9.15. FIRST AID INFORMATION IN SNAKE BITE EMERGENCY:
WHAT TO DO:
1. Allow bite to bleed freely for 1 - 2 minutes.
2. Using a disinfectant, thoroughly clean the wound if possible.
3. Apply hard direct pressure with gauze pad over bite area.
4. Strap pad tightly in place with adhesive tape.
5. Remove tight clothing, shoes, watch or rings.
6. Keep affected extremity as close to heart level as possible.
7. Immobilize affected part, if possible, use a splint.
8. Give plenty of reassurance to the victim.
9. Transport to medical facility as quickly as possible.

WHAT NOT TO DO:
1. Do not use ice or any other type of cooling agent on the bite.
2. Do not apply tourniquets as it may cause gangrenous limb
3. Do not make incisions in the wound.
4. Do not apply electric shock.
5. Do not give anything to eat or drink.
6. Do not apply or inject antisnake venom serum (ASVS) locally

10. Details of manufacturer:
BHARAT SERUMS AND VACCINES LIMITED
Ghar No. 372, Lower Ground Floor, Survey No.14/4(P), 17/2A(P), Thane-Nashik Highway, Nimbavali, Yewai, Bhiwandi - 421302, Dist. Thane, India.
At: Sy. No. 172 Part, Gagillapur (V), Dundigal-Gandimaisamma (M), Medchal Malkajgiri (D), Telangana (State) – 500043, INDIA

11. Details of license number:
TG/MDL/2025-130692.

12. Date of revision:
20 FEB 2026.

Reference:
• Standard Treatment Guidelines, Management of Snake Bite Quick Reference Guide July 2016, Ministry of Health & Family Welfare, Government of India.

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