

*For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.*

# Snake Venom Antiserum I.P.

## Lyophilized

For I.V. Use only

### CAUTION :

Snake bite may cause severe tissue damage or fatal envenomation or both. The physician responsible for treatment of the envenomated patient should be familiar with the contents of this pack insert and the medical literature concerning current concepts of first aid and general supportive therapy.

### COMPOSITION :

Snake Venom Antiserum (Polyvalent) Lyophilized is a refined and concentrated preparation of serum globulins obtained by fractionating blood from healthy hyperimmunised horses. On reconstitution with Sterile Water for Injection as recommended, each ml of the Snake Venom Antiserum neutralises the following quantities of standard venoms tested in mice by intravenous route.

Cobra (Naja naja).....	0.6 mg
Common Krait (Bungarus caeruleus).....	0.45 mg
Russell's Viper (Vipera russelli).....	0.6 mg
Saw-scaled Viper (Echis carinatus).....	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.	

### INDICATIONS :

Snake Venom Antiserum is indicated only for the treatment of envenomation caused by bites of the snakes specified above.

### DOSAGE & ADMINISTRATION :

#### DOSAGE :

Initial dose depends upon an estimate of the amount of envenomation as mentioned below : Minimal Envenomation - Progressive local swelling but no systemic symptoms. 5 vials (50ml) is recommended to be administered.

Moderate Envenomation - Swelling beyond the site of the bite, mild systemic symptoms, and hematologic and coagulation abnormalities are present. 5 to 10 vials (50 to 100ml) is recommended to be administered.

Severe Envenomation - Rapidly progressive and extensive local effects, systemic symptoms and evidence of hemolysis or coagulopathy. 10 to 20 vials (100-200ml) or more is recommended to be administered.

In children and small adults (body weight less than 40kg) upto 50% more doses of Snake Venom Antiserum is recommended to be administered.

### DIRECTIONS FOR RECONSTITUTION :

Reconstitute the Lyophilized Snake Venom Antiserum with 10 ml of Sterile Water for Injection provided with this pack. After adding the diluent, shake the vial gently to dissolve the contents.

### ADMINISTRATION :

Snake Venom Antiserum is administered intravenously either undiluted at the rate of not more than 1ml per minute or is diluted in 500ml 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.

Additional infusions should be repeated hourly until progressive swelling in the bitten part ceases and systemic signs and symptoms disappear. When an adequate dosage is achieved, the improvement in patient's clinical signs are often seen.

**IT IS NOT ADVISABLE TO INJECT SNAKE VENOM ANTISERUM AT THE LOCAL SITE OF BITE.**

**PRECAUTIONS :**

Check the clarity of the reconstituted solution before 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 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) is recommended to be performed in every patient prior to administration regardless of 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.

**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 fever, urticaria, edema, nausea and vomiting. Occasionally neurological manifestations develop. Pain and muscle weakness are frequently present.

**STORAGE :**

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

**PRESENTATION :**

Snake Venom Antiserum I.P. Lyophilized is supplied in vial along with one 10 ml ampoule of Sterile Water for Injection I.P.

**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 clothings, shoes, watch or rings.
6. Keep affected extremity as close to heart level as possible.
7. Immobilise 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.
3. Do not make incisions in the wound.
4. Do not apply electric shock.
5. Do not give anything to eat or drink.

Manufactured in India by :

**BHARAT SERUMS AND VACCINES LIMITED**

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