

SOUTH AFRICAN VACCINE PRODUCERS (Pty) Ltd

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PROPRIETARY NAME

SAIMR POLYVALENT SNAKE ANTISERUM / ANTIVENOM

DESCRIPTIVE NAME:

POLYVALENT SNAKE BITE ANTISERUM / ANTIVENOM (Refined equine serum globulins: *Bites*, *Dendroaspis*, *Hemachatus*, *Naja*)

REGISTRATION NUMBER:

T517 (Act 101/1965)

PHARMACOLOGICAL CLASSIFICATION:

A30.1 ANTIBODIES

SCHEDULING STATUS:

S2

COMPOSITION:

Peppin-refined immunoglobulins, prepared from the serum of horses that have been hyper-immunised with snake venoms. The venoms of the following snakes are used as antigens in the preparation of SAIMR Polyvalent Snake Antivenom: *Bites arietans* (puff adder), *B. gabonica* (gaboon adder), *Hemachatus hemachatus* (rinkhals), *Dendroaspis angusticeps* (green mamba), *D. jamesoni* (Jameson's mamba), *D. polypleps* (black mamba), *Naja nivea* (Cape cobra), *N. melanoleuca* (forest cobra), *N. annulifera* (spotted cobra), *N. mosambica* (Mozambique spitting cobra).

Contains: 4 0.35% w/v Cresol as preservative.

IDENTIFICATION:

A light yellow to light brown clear liquid.

PHARMACOLOGICAL ACTION:

Neutralises the venom of specific snakes.

INDICATIONS: For the treatment of snake bite as follows:

The serum is effective against the venoms of the rinkhals, mambas and all the cobras and vipers (adders) likely to cause life-threatening envenomation in Southern and Central Africa. The serum is ineffective AND SHOULD NOT BE USED in treatment of bites caused by the berg adder (*Bites caudata*), the horned adder (*Bites caudata*), the many horned adder (*Bites cornuta*), the night adder (*Causus* spp.), the burrowing asp (*Atractaspis* spp.), back fangers snakes (boomslang, vine snake) or any other snake.

CONTRA-INDICATIONS:

Significant allergic disease, or a history of an adverse reaction to the injection of horse serum, is a relative contra-indication in the absence of adrenalin pre-medication. Consider risk versus benefit (see also under side effects and special precautions).

DOSAGE AND DIRECTIONS FOR USE:

Everyone bitten by a snake should be referred to a hospital or doctor whether he is treated in the field or not. Treatment with serum should take place under medical supervision whenever possible.

BEFORE INJECTING, CARRY OUT THE INITIAL FIRST AID PROCEDURES AS DETAILED BELOW:

THE PRESSURE BANDAGE:

THIS IS CONTRA-INDICATED IN BITES BY CYTOTOXIC SNAKES, e.g. adders, stiletto snakes and spitting cobras. In all other cases of snake bite, a broad bandage, preferably a crepe bandage, should be applied as soon as possible around the limb, covering the bitten area and as much of the limb as possible. This may be supplemented with other material, e.g. a strip torn off a shirt. It should be applied as tightly as one would bind a sprained ankle. The limb must be kept as still as possible by splinting with wood, cardboard, rolled newspaper, or any available rigid material and the patient should move as little as possible.

ARTERIAL TOURNIQUET:

The use of a tourniquet is not recommended, except under special circumstances. It should never be used in viper (adder) bites, but it will delay general poisoning by the venoms of the more dangerous elapid snakes (e.g. black mamba) if the nearest medical assistance is several hours away. The tourniquet (bell, strap or rubber bandage) should be placed as soon as possible on the upper arm or above the knee, depending on the site of the bite. It should be applied firmly enough to occlude the pulse at the wrist or ankle, but should not be left on for more than about one and a half hours, and released for a few seconds every 15 - 30 minutes. The momentary release of the tourniquet may allow more venom to enter the general circulation, which may aggravate the patient's symptoms. It should be discarded altogether as soon as an adequate dose of antivenom has been injected intravenously. It should not be applied when more than an hour has elapsed since the bite.

SNAKE VENOMS:

These can be classified as follows:

1. Haemotoxic (boomslang, vine snake), causing bleeding due to a coagulation defect.
2. Cytotoxic (adders, spitting cobras and stiletto snakes), cause extensive painful swelling around the site of the bite with possible tissue destruction.
3. Neurotoxic (cobras, mambas) causing paralysis of the muscles including those required for swallowing & respiration.

GENERAL TREATMENT:

Keep the patient quiet and comfortably warm and avoid unnecessary movement. Small amounts of water, tea or coffee may be given if the patient has no difficulty with breathing and swallowing. Artificial respiration may become necessary if bitten by a neurotoxic snake. All patients should be taken to a hospital or doctor as quickly as possible whether they have received serum or not. Incisions are not recommended. Suction may be applied to the fang marks. A mechanical suction device is enclosed in each Snakebite Outfit. Cover the area with a sterile dressing or clean handkerchief or tissue. A patient bitten by an unidentified snake should be observed for 24 hours.

SERUM TREATMENT:

Any injection of serum carries a risk and as far as possible should be left to a doctor, preferably in a hospital, who would be able to inject the serum by the most effective route, i.e. directly into the blood stream. It may be necessary, however, for a lay person to inject serum, in which case the procedure would be as follows:

The tip of the ampoule should be snapped off (see instruction enclosed with ampoule) and the contents drawn into a sterile syringe. The skin should be sterilized with the swab supplied in the Snakebite Outfit or any other suitable disinfectant, but time should not be wasted looking for one. The needle of the syringe is inserted under the skin or preferably into a muscle and the contents of one ampoule slowly expelled. The needle is then withdrawn, the syringe refilled and the contents given in the same way at another site. When the patient is in a critical state and particularly when the snake is a cobra or a mamba, the serum should be injected intravenously but this route should be used **only** by trained medical personnel. The initial dose should be at least the contents of two ampoules, but the condition of the patient may demand the injection of up to four or five times as much. The serum should be at room temperature when given intravenously, as a slow bolus injection or as an infusion diluted in 50 - 100 ml of normal saline or 5 % dextrose water over 5 - 10 minutes, with the patient recumbent during the injection, and for at least one hour afterwards. Local injection around the bite is not recommended. The dose of serum required depends on the amount of venom injected by the snake, not on the size of the victim and should not be reduced in the case of children.

SPITTING SNAKES:

The rinkhals and the spitting cobras may cause a severe inflammatory reaction if their venom enters the eyes. Wash liberally with water, milk or any non-irritant fluid. If the reaction is severe and fails to respond to washing, SAIMR Polyvalent Antivenom diluted with water (1:5 to 1:10) may be used as an eye-wash.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

The injection of even highly purified serum carries a risk of allergic/hypersensitivity reactions. Anaphylaxis is non-dose related and characterized by cardiovascular collapse, laryngeal oedema and bronchospasm within 1 - 15 minutes (occasionally up to 6 hours) of administration. The risk of this type of reaction in a healthy individual is slight, but those with an allergic disposition, in particular a history of asthma or infantile eczema, or previous allergic reactions to horse serum, should not receive the antivenom unless it is absolutely necessary. Antivenom should be administered with extreme caution in these cases. Treatment of anaphylaxis includes the administration of adrenaline and support of vital functions. Depending on the severity of previous allergic reactions, some authorities advocate the prophylactic use of intramuscular adrenaline (1:1000 solution or 1 mg/ml) in a dose of 0.25 - 0.5 ml in adults and 0.1 ml in children. However the potential risk of cardiovascular complications due to adrenaline administration should be taken into consideration. Serum sickness is characterized by urticaria, poly-arthritis or peri-articular oedema, mild fever and lymphadenopathy. Management includes the use of antihistamines and steroids. After administration of antivenom, the patient should be kept under observation for 6 hours and adrenaline kept in readiness for emergency use. It is important to note that premedication with antihistamines and corticosteroids does not prevent an acute anaphylactic reaction, but may decrease the incidence or severity of allergic manifestations, such as urticaria.

Test dose: Skin testing or conjunctival testing for the possibility of hypersensitivity, by injection or drops of diluted or undiluted antivenom, is not recommended since it is unreliable in predicting reactions to the main dose.

PREGNANCY AND LACTATION:

Pregnancy and lactation are not contra-indicated to antivenom use. Consider risk versus benefit.

INTERACTIONS:

No significant drug interactions are anticipated with the use of antivenoms.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

None. Treat symptomatically. See also serum sickness.

PRESENTATION:

1. Packed as individual 10 ml ampoules.
2. A Snakebite Outfit containing two 10 ml ampoules, pressure bandage, tourniquet, syringe and needle, suction syringe, antiseptic swab.

STORAGE DIRECTIONS:

Store at 2 °C to 8 °C. Freezing of the antivenom will not affect its potency, but may cause the ampoule to crack.

OTHER ANTIVENOMS PRODUCED BY SOUTH AFRICAN VACCINE PRODUCERS (PTY) LTD:

- Boomslang Antivenom
- Echis carinatus/ocellatus* (saw-scaled viper) Antivenom
- Scorpion Antivenom (*Parabuthus* species)
- Spider Antivenom (*Latrodectus* species)

NAME AND BUSINESS ADDRESS OF APPLICANT:

SOUTH AFRICAN VACCINE PRODUCERS (PTY) LTD, 1 Modderfontein Rd, Edenvale, Gauteng. PO Box 28999, Sandringham 2131.

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ANTIELE TOEKEN:

Die gebruik van die antivenom moet slegs beperk tot die spesifieke doeleindes. Dit moet nooit gebruik word by ander blywende of tydelike wondwonders. Die gebruik van die antivenom moet slegs beperk tot die spesifieke doeleindes. Dit moet nooit gebruik word by ander blywende of tydelike wondwonders. Die gebruik van die antivenom moet slegs beperk tot die spesifieke doeleindes. Dit moet nooit gebruik word by ander blywende of tydelike wondwonders.

SLANG VENENE:

- Kan geklassifiseer word as volg:

 1. Hemotoksies (boomslang, voëlslang) veroorsaak bloedinge en slym.
 2. Neurotoksies (doders, spogkobras en spyslang) veroorsaak argus.
 3. Neurotoksies (kobras, mambas) veroorsaak spierverlamminge, spook en dood.

ALGEMEEN BEHANDELING:

Die eerste teken van 'n ernstige reaksie is 'n warm en verrye, rooie beweging van die wond. Koffie of tee mag nie geëet word. 'n klein hoeveelheid koffie of tee mag geëet word. 'n klein hoeveelheid koffie of tee mag geëet word. 'n klein hoeveelheid koffie of tee mag geëet word.

TOEDIENING VAN ANTIVENOM:

Enige toediening van antivenom moet slegs deur 'n dokter of 'n dokter in 'n hospitaal opneem, waar dit in die bloedsomloop toegelê kan word. Enige toediening van antivenom moet slegs deur 'n dokter of 'n dokter in 'n hospitaal opneem, waar dit in die bloedsomloop toegelê kan word.