SOUTH AFRICAN VACCINE PRODUCERS (Pty) Ltd

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Proprietary name:

SAIMR SCORPION ANTIVENOM

Descriptive Names:
Refined equine serum globulins

Registration No:
T518 (Act 101/1965)

Pharmacological classification:
A30.1. Antibodies

Scheduling Status:
S4

Composition:
Purified, concentrated equine immune globulins, in ampoules of 5 ml, with less than 0,35% v/v cresol. The concentrated preparation of serum globulins is obtained by fractionating blood from horses immunized with *Parabuthus transvaalicus* venom.

Identification:
Clear, almost colourless or faintly yellow liquid, having a slight odour due to the cresol.

Pharmacological action:
The immune globulins neutralise the venom of *Parabuthus* scorpion species. Scorpion venom contains neurotoxins that act on voltage sensitive Na+-channels of peripheral neurons, causing hyperactivity of somatic and autonomic nerves.

Indications:
Treatment of patients with systemic manifestations of *Parabuthus* scorpion stings (syndrome known as scorpionism). These include paraesthesias and hyperaesthesias, dysphagia and dysarthria. Involuntary movements, tremors and fasciculations are prominent. Hyperactivity and restlessness are common, especially in children. Stretch reflexes are brisk. Most patients experience a decrease in motor power and have difficulty in standing up, or walk with an ataxic gait. Fifty percent of patients may have difficulty in breathing, some requiring ventilatory support. Symptoms and signs of autonomic nervous system stimulation include: profuse sweating, raised temperature, copious oral and upper respiratory secretions, as well as a raised blood pressure. Ptosis and visual disturbances may be present. Pain at the *Parabuthus* sting site is severe and often described as burning and of an excruciating intensity. Note, however, that all scorpion stings will cause local pain of varying intensities. The local sting site of all scorpion species is often not visible and, if present, the surrounding inflammatory reaction is mild or insignificant. Local pain, without systemic symptoms and signs of envenomation, is not an indication for antivenom administration. Scorpionism (systemic symptoms and signs of scorpion envenomation) is sometimes difficult to distinguish from latrodectism. Consult the Tygerberg Poison Information Centre. The "SAIMR Scorpion Antivenom" is effective only in the treatment of scorpionism caused by *Parabuthus* scorpion stings.

Contra-indications:
Significant allergic disease states or a history of hypersensitivity to horse serum, are relative contra-indications. Consider risk versus benefit. (See also under side-effects and special precautions).

Dosage and directions for use:
Administer 10 ml intravenously. The intramuscular route should only be considered if intravenous administration *is not possible*. If relief has not been obtained within four to six hours, an additional 5 ml may be given. The antivenom should be administered as a slow intravenous bolus injection (3–5 minutes) or diluted in 50–100 ml normal saline or 5% dextrose water and infused over 5–10 minutes. The dose is the same for children as for adults. (For more information refer to The Diagnosis and Treatment of Envenomation in South Africa by Schrire L, Müller GJ and Pantanowitz L; SAIMR).

Side-effects and special precautions:
Injection of purified serum carries the risk of allergic/hypersensitivity reactions. The most common reaction, serum sickness, is dose related and may occur about 5 days to three weeks (usually 7–12 days) after injection. Serum sickness is characterised by urticaria, poly-arthritis or peri-articular oedema, mild fever and lymphadenopathy. Management includes the use of antihistamines and corticosteroids. Acute anaphylaxis, a more serious complication, is non-dose related and characterised 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 for 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 absolutely necessary. Antivenom should be administered with extreme caution in these cases. Treatment for anaphylaxis includes 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. 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 skin manifestations, such as urticaria. Skin testing for the possibility of hypersensitivity, by injecting a trial dose of diluted antivenom intradermally, is not recommended since it is unreliable and may in itself induce an anaphylactic reaction.

Pregnancy and lactation:
Pregnancy is not a contra-indication for the administration of antivenom; consider risk versus benefit. It is safe to use in breast-feeding women.

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

Known symptoms of overdose and particulars of treatment:
None. Treat symptomatically. See also serum sickness.

Presentation:
Packed as individual 5 ml ampoules.

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. Exposure to higher temperatures will cause a marked loss in potency, accompanied by cloudiness, which makes the antivenom unsuitable for use.

Name and business address of applicant:
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