Product Information

APPROVED NAME

RED BACK SPIDER ANTIVENOM

AUST R 74893

DESCRIPTION

RED BACK SPIDER ANTIVENOM is prepared from the plasma of horses immunised with the venom of the female red back spider (*Latrodectus hasselti*). Each vial contains 500 units of antivenom which has been standardised to neutralise 5 mg of venom. The product also contains phenol, sodium chloride and other equine plasma proteins in an aqueous solution.

PHARMACOLOGY

RED BACK SPIDER ANTIVENOM is a concentrated solution of purified globulins derived from horse plasma which contains specific antibodies against the toxic substances in the venom of the red back spider (*Latrodectus hasselti*).

The effects of the venom, particularly severe pain, may persist for days or even weeks and there are reports of satisfactory use of the antivenom to alleviate these symptoms up to 10 days after a confirmed red back spider bite.

INDICATIONS

For the treatment of patients who exhibit manifestations of systemic envenoming following a bite by a red back spider (*Latrodectus hasselti*).

CONTRAINDICATIONS

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.

See PRECAUTIONS for use of RED BACK SPIDER ANTIVENOM in patients with a known allergy.

PRECAUTIONS

When medicinal products prepared from animal plasma are administered, infectious diseases due to the transmission of infective agents cannot be totally excluded. This applies to pathogens of hitherto unknown origin. This possibility must always be considered and should be conveyed, whenever possible, to patients who may receive the product. Historically there have been no known recorded cases of transmission of viruses by this product.

As this product is prepared from animal serum, severe allergic reactions may follow, including anaphylactic shock, though this is uncommon. A syringe already loaded with 1:1000 adrenaline must be available during antivenom therapy. Anaphylactoid reactions are more likely to occur in those who are atopic or who have previously received horse serum.This would include patients who received Tetanus Antitoxin prior to 1974. Premedication with adrenaline and intravenous antihistamine may be of help, particularly in those who are known to be at risk. The routine use of such premedication is controversial. The results of initial skin testing are not satisfactory and should not be undertaken.

Symptoms and signs of anaphylaxis include pallor, tachycardia, urticaria, angioedema, cough and dyspnoea due to laryngeal oedema or bronchospasm. Nausea, vomiting and abdominal pain are less common. Typical signs of shock may develop in 1 to 2 minutes and the patient may convulse, become unresponsive and die.

Should anaphylaxis occur, the administration of antivenom should be stopped and 0.3 to 0.5 mL of 1:1000 adrenaline should be injected subcutaneously (0.01 mL/kg in children). This can be repeated after 2 to 3 minutes if necessary. In severe cases, intravenous antihistamine may be of help, together with intravenous corticosteroids to avoid late reactions. Further administration of antivenom should be considered in the light of the relative problems of envenoming and anaphylaxis.

Severe cases of systemic envenoming should be managed in an intensive care unit. Although the local effects of envenomation (severe pain, erythema, swelling and sweating) may occur in the first hour, severe systemic effects may not occur until 12 hours after envenoming.

Delayed serum sickness can occur following the use of animal derived antivenoms. The most common manifestations include fever, cutaneous eruptions, arthralgia, lymphadenopathy and albuminuria. Less commonly, arthritis, nephritis, neuropathy and vasculitis can occur. The condition usually appears 8-13 days after the use of antivenom but can occur as soon as 12 hours after a second injection of a similar animal protein.

The incidence of serum sickness is greater with larger volumes of antivenom, but can be expected to occur in at least 5% of patients receiving horse serum for the first time.

Use in pregnancy

There is limited, but inconclusive information on the use of the product in pregnant women.

Use in lactation

No information is available on the use of the product during lactation.

ADVERSE REACTIONS

As the product is of animal origin, severe allergic reactions can occur (see PRECAUTIONS). A survey of over 2000 red back spider bites revealed an incidence of anaphylactic reactions to the antivenom of 0.5%, of which none was fatal. In 44 patients who received undiluted antivenom intravenously, five patients developed anaphylactic reactions (11%). In 2073 patients who received intramuscular injections, there were six cases (0.3%).

The following adverse events were also reported:

Hypersensitivity and skin	*Uncommon:*	Rash
		Urticaria
		Delayed serum sickness
		Local injection site reactions
Haematological	*Rare:*	Lymphadenopathy
Musculoskeletal	*Rare:*	Myalgia
		Rhabdomyolysis
General	*Rare:*	Cyanosis
		Fever
		Chest pain

As the recording of adverse events was by means of forms which were, in most cases, returned within 24 hours of administration of the antivenom, the actual incidence of serum sickness may be higher than is reported here.

DOSAGE AND ADMINISTRATION

A large proportion of people bitten by red back spiders have symptoms that are so mild that antivenom is not necessary. When there is evidence of severe local and/or systemic envenoming by a red back spider, the contents of one vial (500 units) should be given intramuscularly. The dose is the same for both adults and children.

In cases of life threatening envenoming, the intravenous route may be used, first diluting the antivenom 1:10 in Hartmann's Solution. **NOTE: The intravenous route is more likely to precipitate anaphylactoid reactions.**

If the effects of the venom have not been completely reversed in two hours, a second injection of antivenom may be necessary providing it is safe to do so. In a few cases further doses may be needed as symptoms of envenoming can sometimes last for long periods after the bite. It is unusual to require more than three vials of antivenom. If after three vials there has been no improvement in symptomatology, consider the possibility the bite was not by a red back spider. It may occasionally be necessary to treat both envenoming and anaphylaxis simultaneously.

Before giving the injection of antivenom, a separate syringe should be loaded with 1:1000 adrenaline, as anaphylactic reactions can occur rapidly (see PRECAUTIONS).

If a severe reaction occurs, 0.3 - 0.5 mL of 1:1000 adrenaline (0.01 mL/kg in children) should be injected subcutaneously, and repeated as necessary.

RED BACK SPIDER ANTIVENOM contains no antimicrobial preservative. Use once only and discard any residue.

OVERDOSAGE

No information is available on overdosage.

PRESENTATION

RED BACK SPIDER ANTIVENOM is available as vials containing 500 units of antivenom in 1.0 to 1.5 mL of aqueous solution.

STORAGE

RED BACK SPIDER ANTIVENOM should be protected from light and stored at 2-8°C. Do not freeze.

NAME AND ADDRESS OF SPONSOR

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