Product Information

NAME OF THE MEDICINE

FUNNEL WEB SPIDER ANTIVENOM AUST R 31847

DESCRIPTION

FUNNEL WEB SPIDER ANTIVENOM is prepared from the plasma of rabbits immunised with the venom of the male funnel web spider (*Atrax robustus*). Each vial of the product contains 125 units of antivenom which has been standardised to neutralise 1.25 mg of funnel web spider venom. The product also contains glycine, other rabbit plasma proteins, sodium chloride, sodium phosphate – dibasic and sodium phosphate – monobasic. It is presented as a freeze dried powder for reconstitution.

Pharmacology

FUNNEL WEB SPIDER ANTIVENOM is a purified immunoglobulin (mainly immunoglobulin G), derived from rabbit plasma, which contains specific antibodies against the toxic substances in the venom of the funnel web spider, *Atrax robustus*.

There is evidence to show that the antivenom is effective in the treatment of patients bitten by some other funnel web spiders of the *Hadronyche* genus (formerly *Atrax*).

INDICATIONS

For the treatment of patients who exhibit manifestations of systemic envenoming following a bite by a funnel web spider.

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 FUNNEL WEB 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.

If the patient has received effective first aid (firm bandaging and a splint), symptoms and signs of envenoming may not become apparent until removal of the bandage but may then develop rapidly.

Removal of the bandage and splint may precipitate the systemic effects of the venom in patients who have been bitten.

These typically consist of severe local pain, nausea, vomiting, abdominal pain, profuse sweating, salivation, lachrymation and severe dyspnoea. Mental confusion leading to coma may occur as well as hypertension and pulmonary oedema. Local and general fasciculation of muscles is usually present.

A proportion of people bitten by funnel web spiders have symptoms that are so mild that antivenom is not necessary.

The patient should be observed for signs of envenoming for at least four hours after being bitten or after removing the pressure bandage before a decision is made not to administer the antivenom.

As systemic effects of the venom can occur rapidly it may be necessary to give symptomatic treatment with drugs such as atropine and muscle relaxants until the antivenom is effective.

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 rabbit serum.

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 skin testing to determine patients who may have an allergic reaction are not satisfactory and should not be undertaken.

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 envenomation and anaphylaxis.

Severe cases of systemic envenoming should be managed in an intensive care unit.

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.

Use in pregnancy
There is no information of the use of this product in pregnant women.

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

ADVERSE REACTIONS

The following adverse reactions, presented below according to System Organ Class and frequency, have been identified during post approval use of CSL FUNNEL WEB SPIDER ANTIVENOM. Adverse event frequencies are defined as follows:
Very common: ≥1/10; common: ≥1/100 and <1/10; uncommon: ≥1/1000 and <1/100; rare: ≥1/10,000 and <1/1000; and very rare: <1/10,000.

Immune system disorders
Common: Allergic reactions including anaphylactic shock and delayed serum sickness

Skin and subcutaneous tissue disorders
Common: Urticaria, rash

DOSAGE AND ADMINISTRATION

The dose of FUNNEL WEB SPIDER ANTIVENOM is dependent on the extent of envenoming. The recommended initial dose is 2 vials of FUNNEL WEB SPIDER ANTIVENOM. Each vial is reconstituted with 10 mL of Water for Injections BP. Gently swirl to ensure the product is fully dissolved; the vial may be inverted to assist dissolution. A clear to slightly opalescent colourless solution is typically obtained within 10 minutes. After complete dissolution the product must be used immediately. FUNNEL WEB SPIDER ANTIVENOM should be administered by slow intravenous injection.

The dose is the same for both adults and children.

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.

It may occasionally be necessary to treat both envenoming and anaphylaxis simultaneously.

If the effects of the venom have not been completely reversed, the dose of antivenom may be repeated in 15 minutes, providing it is safe to do so. In a few cases, further doses may be needed.

A proportion of people bitten by funnel web spiders have symptoms that are so mild that antivenom is not necessary. It is estimated that the proportion of those bitten by funnel web spiders who become seriously ill is between 1 in 5 and 1 in 10. First aid with pressure bandaging and immobilisation tends to delay the onset of the illness and may allow local detoxification. **Removal of the bandage may precipitate the onset of symptoms and signs of envenoming**.

The patient should be observed for signs of envenoming for at least four hours after being bitten or after removing the pressure bandage before a decision is made not to administer the antivenom.

FUNNEL WEB SPIDER ANTIVENOM contains no antimicrobial preservative. Use once only and discard any residue.

OVERDOSAGE

No information is available on overdosage. Contact the Poisons Information Centre on 131 126 for further advice on overdosage management.

PRESENTATION

FUNNEL WEB SPIDER ANTIVENOM is available as a freeze dried preparation containing 125 units of antivenom as approximately 100mg immunoglobulin dispensed in 20mL glass containers.

STORAGE

FUNNEL WEB SPIDER ANTIVENOM should be protected from light and stored below 8°C (Refrigerate). The reconstituted product must be used immediately.

NAME AND ADDRESS OF SPONSOR

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Date of first inclusion in the Australian Register of Therapeutic Goods: 4 November 1991

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