Product Information

APPROVED NAME

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 and other rabbit plasma proteins. 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.

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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.

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 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

As the product is of animal origin, severe allergic reactions are possible (see **PRECAUTIONS**). There has been a single spontaneous report to the manufacturer of a severe anaphylactoid reaction following administration of this product. The patient responded to standard medical management of severe anaphylactoid reaction.

It should be borne in mind that although the antivenom has been available for a number of years, there are probably less than 1500 cases where it has been used and it is unlikely that anyone would have received a dose of rabbit serum on more than one occasion.

As the recording of adverse events is principally by means of report forms which are, in most cases, returned within 24 hours of administration of the antivenom, the incidence of serum sickness is unknown.

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 reconstituted with the volume of Water for Injections BP indicated on the label (up to 10.5 mL) and should be administered by slow intravenous injection.

The dose is the same for both adults and children.

After reconstitution the product must be used immediately.

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.

PRESENTATION

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