Product Information

APPROVED NAME

STONEFISH ANTIVENOM

AUST R 74892

DESCRIPTION

STONEFISH ANTIVENOM is prepared from the plasma of horses immunised with the venom of the stonefish (*Synanceia trachynis*). Each vial contains 2,000 units of antivenom. The product also contains phenol, sodium chloride, and other equine plasma proteins in an aqueous solution.

PHARMACOLOGY

Stonefish are found throughout Australian tropical waters. They prefer calm, shallow water around coral islands, estuaries and sheltered bays. They settle into depressions in the mud or sand of the sea bed and become almost indistinguishable from surrounding rock or coral. The stonefish has poisonous spines along its back which are used only in defence. Those who are stung are usually people who inadvertently stand on the fish; less commonly, the damage is caused when an attempt is made to pick up a stonefish believing it to be a piece of rock or coral.

The stonefish has thirteen dorsal spines, each of which possesses a pair of venom glands. The venom of the stonefish is heat labile. It possesses a permeability-increasing enzyme which causes considerable local oedema. This enzyme is believed to be also responsible for pulmonary oedema which can occur following a stonefish sting. Other systemic effects which have been described include hypotension, bradycardia, arrhythmia, fever, muscle weakness and paralysis.

The first and overwhelming local effect of the sting is excruciating pain. The pain, together with redness and swelling, will often spread up the limb and involve regional lymph nodes.

The systemic effects described earlier can also occur but do not appear to be common.

INDICATIONS

For the treatment of patients who, following envenoming by a stonefish, have systemic manifestations or severe oedema and pain which do not respond to first aid measures.

CONTRAINDICATIONS

There are no absolute contraindications, but the product should not be used unless there is clear evidence of stonefish envenoming with severe effects.

See PRECAUTIONS for the use of STONEFISH 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.

Neither tourniquets nor compression immobilisation bandages should be applied to those who have received stonefish wounds as retardation of the venom at the site will increase local pain and tissue damage.

As this product is prepared from animal plasma, severe allergic reactions may follow, including anaphylactic shock. A syringe already loaded with adrenaline 1:1,000 must be available during antivenom therapy. Anaphylactic reactions are more likely to occur in those who are atopic or who have previously received equine serum. This would include patients who have previously received equine Tetanus Antitoxin (prior to 1974 in Australia). Some authorities have advocated premedication with subcutaneous adrenaline and intravenous antihistamine, particularly in those patients who are known to be at risk, but such use is controversial.

The results of initial skin testing to determine patients who may have an allergic reaction to antivenom 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, cease administration of antivenom, administer oxygen and inject adrenaline 1:1,000 intramuscularly at the following dose rates: small adults (<50 kg) 0.25 mL, average adults (50-100 kg) 0.5 mL, large adults (>100 kg) 0.75 mL. For children (to age 12) use 1:10,000 and inject 0.25 mL per year of age. If there is little or no response to the initial intramuscular dose of adrenaline, administer the same dose (diluted to 1:10,000) slowly into an intravenous line. Repeat at 5 minute intervals depending on response. In severe cases, intravenous antihistamine and intravenous corticosteroids may also be given to reduce the chance of late reactions, but have a slower onset of action than adrenaline. Further administration of antivenom should be considered in the light of the relative problems of envenoming and anaphylaxis.

Severe cases of envenoming should be managed in an intensive care unit, if possible.

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 to 13 days after the use of antivenom but can occur as soon as 12 hours after a second injection of horse protein.

The incidence of serum sickness is greater with larger volumes of antivenom.

Use in pregnancy

There is no information on the safety of the product in pregnant women.

Use in lactation

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

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ADVERSE REACTIONS

As this product is of animal origin, severe allergic reactions can occur (see PRECAUTIONS). The only reported adverse events are of 2 cases of delayed serum sickness amongst 15 patients who were followed up after administration of the antivenom. It should be borne in mind that although the antivenom has been in use for many years, the number of treated cases is small. 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 is unknown.

DOSAGE AND ADMINISTRATION

The majority of people who stand on stonefish and whose feet are pierced by their spines will need antivenom for relief of the pain and oedema. However, as the toxin is heat labile, immersion of the limb in hot water (50°C) should be undertaken first as this usually gives some pain relief. As the patient will often be irrational as a result of the pain, the temperature of the water should be judged by the attendant, rather than the patient, to avoid scalding. Injection of local anaesthetic around the sting or as a regional block may also help to reduce the pain.

The initial dose of antivenom depends on the number of visible puncture sites:

- 1 - 2 punctures 1 vial (2,000 units)
- 3 - 4 punctures 2 vials (4,000 units)
- 5 or more punctures 3 vials (6,000 units)

The dose is the same for both adults and children.

The antivenom should be given by intramuscular injection but may be given by intravenous infusion in extreme cases after diluting the antivenom 1:10 in an intravenous solution. **NOTE: The intravenous route is more likely to precipitate anaphylactoid reactions.**

Some authorities have advocated premedication with 0.25 mL of 1:1,000 adrenaline subcutaneously and intravenous antihistamine to reduce the chance of anaphylactic shock, particularly in those patients who are known to be at risk, but such use is controversial (see PRECAUTIONS).

The patient should receive the antivenom in an intensive care unit if possible.

If the initial dose of antivenom is insufficient to control the effects of the venom and the identity of the stonefish is assured, the initial dose of antivenom should be repeated.

The patient must be monitored for at least 6 hours after the receiving the antivenom.

Before giving the antivenom, a separate syringe should be loaded with 1:1,000 adrenaline, as anaphylactic reactions can occur rapidly (see PRECAUTIONS).

Should an anaphylactic reaction occur, cease administration of antivenom, administer oxygen and inject adrenaline 1:1,000 intramuscularly at the following dose rates: small adults (<50 kg) 0.25 mL, average adults (50-100 kg) 0.5 mL, large adults (>100 kg) 0.75 mL. For children (to age 12) use 1:10,000 and inject 0.25 mL per year of age. If there is little or no response to the initial intramuscular dose of adrenaline, administer the same dose (diluted to 1:10,000) slowly into an intravenous line. Repeat at 5 minute intervals depending on response.

As delayed serum sickness is relatively common following the use of large volumes of foreign protein, it is advisable to administer a corticosteroid either by a single intravenous injection or orally for 4 to 5 days to children and to those receiving multiple doses of antivenom.

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

STONEFISH ANTIVENOM contains no antimicrobial preservative. Use once only and discard any residue.

OVERDOSAGE

No information is available on overdosage.

PRESENTATION

STONEFISH ANTIVENOM is available as vials containing 2,000 units in 1.5 to 3 mL of aqueous solution.

STORAGE

STONEFISH ANTIVENOM should be protected from light and stored between 2 to 8°C. Do not freeze.

NAME AND ADDRESS OF SPONSOR

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