Product Information

NAME OF THE MEDICINE

STONEFISH ANTIVENOM AUST R 74892

DESCRIPTION

STONEFISH ANTIVENOM is prepared from the plasma of horses immunised with the venom of stonefish *(Synanceia verrucosa* and/or *Synanceia horrida)*. 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.

Appropriate first aid measures recommended by local guidelines must be instituted when necessary before giving antivenom.

As this product is prepared from animal plasma, severe allergic reactions may follow, including anaphylactic shock. Adrenaline must be available during antivenom therapy and prepared ready for use prior to antivenom administration. 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). In the past, 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.

Should anaphylaxis occur, suspend administration of antivenom and implement treatment measures immediately according to an appropriate protocol or guideline. 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 can appear days or weeks after the use of antivenom but can occur as soon as 12 hours after a second injection of horse protein. Patients should be advised of the symptoms of serum sickness and warned to seek urgent medical attention if such symptoms develop.

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. It is advisable to carefully weigh the risks of untreated envenoming against the expected benefits and potential risks of antivenom administration.

Use in lactation

No information is available on the use of this product during lactation. It is advisable to carefully weigh the risks of untreated envenoming against the expected benefits and potential risks of antivenom administration.

ADVERSE EFFECTS

The following adverse reactions, presented below according to System Organ Class and frequency, have been identified during post-approval use of CSL antivenoms. 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 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 appropriate first aid measures recommended by local guidelines must be instituted when necessary before giving antivenom.

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 such as Hartmann's Solution or 0.9% w/v Sodium Chloride. Seek expert advice regarding dilution of antivenom to avoid fluid overload, as required. **NOTE: The intravenous route is more likely to precipitate anaphylactoid reactions.**

In the past, 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 and always in a setting where resuscitation facilities are immediately available.

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, adrenaline should be prepared ready to use, as anaphylactic reactions can occur rapidly (see PRECAUTIONS).

Should an anaphylactic reaction occur, suspend administration of antivenom and implement treatment measures immediately according to an appropriate protocol or guideline.

As delayed serum sickness is relatively common following the use of large volumes of foreign protein, patients who have received antivenom should be advised of the symptoms of serum sickness and warned to seek urgent medical attention if such symptoms develop.

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. Contact the Poisons Information Centre on 131 126 for further advice on overdosage management.

PRESENTATION AND STORAGE CONDITIONS

Presentation: STONEFISH ANTIVENOM is available as vials containing 2,000 units in aqueous solution. The product volume is potency dependant thus it varies from batch to batch. Please refer to the product volume printed on the carton.

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

NAME AND ADDRESS OF THE SPONSOR

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POISION SCHEDULE OF THE MEDICINE

Prescription Only Medicine (S4)

Date of first inclusion in the Australian Register of Therapeutic Goods: 15 December 2009

Date of Most Recent Amendment: 2 June 2017