Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Stonefish Antivenom.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Stonefish Antivenom against the benefits they expect it will have.

If you have any concerns about this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Stonefish Antivenom is used for

What it is used for

Stonefish Antivenom is given to those people who become ill after being poisoned by a stonefish.

The stonefish has sharp spines along its back. Standing on a stonefish causes these spines to pierce the skin on the bottom of the foot. Poison from the stonefish goes into the foot along the spines and causes intense pain, severe damage to the foot and can cause serious illness.

The antivenom is given to neutralise the poison, prevent dangerous illness and to reduce the pain and swelling.

Before antivenom is given, first aid measures must be used.

Not everyone who is stung needs the antivenom, but the pain and swelling is usually so severe in those people who stand on stonefish that antivenom is usually required to control these effects. In these people it is essential to use an appropriate amount of antivenom to counteract the effects of the poison.

How it works

Stonefish Antivenom is an injection designed to help neutralise the effect of the poison (venom) of the stonefish.

It is made by immunising horses against the venom of the stonefish and then collecting that part of the horse's blood which neutralises this poison.

The antivenom is purified and made into an injection for people who may need it after receiving a stonefish sting.

Ask your doctor if you have any questions about why this medicine has been given to you.

Before you are given Stonefish Antivenom

When you must not be given it

As there are sometimes unpleasant and dangerous reactions to the antivenom (see Side Effects), it should not be given to people who have no effects from the sting. However as Stonefish Antivenom can be important in relieving the pain and other severe effects of the poison, it should not be withheld from anyone who needs it.

Before you are given it

Tell your doctor if:

- 1. you have allergies to:
- · any other medicines
- any other substances such as foods, preservatives or dyes.
- 2. you have, or have had any medical conditions, especially the following:
- asthma
- · hayfever.
- you have ever had injections made from horse serum (snake bite and other antivenoms).
- 4. you had an anti-tetanus injection before 1974.
- you are pregnant or you are breast feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Stonefish Antivenom.

How Stonefish Antivenom is given

How much is given

The dose is the same for both adults and children, and depends on the number of puncture sites from the spines of the stonefish:

- for 1 2 punctures the dose is 1 vial (2,000 units)
- for 3 4 punctures the dose is 2 vials (4,000 units)
- for 5 or more punctures the dose is 3 vials (6,000 units).

The injection can be repeated as necessary.

Your doctor will take precautions to counteract any allergic reactions if they should happen.

How it is given

This medicine is usually injected into a muscle, or in severe cases may be diluted and given via a vein.

Stonefish Antivenom does not contain any antimicrobial preservative. It should be used once and any residue discarded.

After having Stonefish Antivenom

When medicines are produced in animals and injected into you, it is always possible that viruses or other substances could be present in the medicine and cause an illness. These could be viruses or other infectious agents which may not yet have been discovered. In the past, there have been no reports of this ever having happened with this product.

If you have any queries about any aspect of this medicine, or questions regarding information in this leaflet, discuss them with your doctor or pharmacist.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having Stonefish Antivenom.

It may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time

they are not. You may need medical treatment if you get some of the side effects.

As the injection is made from horse serum, side effects occur more commonly in those who have allergies, particularly if they have ever had injections before which were also prepared from horses. Allergic reactions can be treated by your doctor.

Ask your doctor or pharmacist to answer any questions you have.

Tell your doctor immediately if you notice any of the following:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- fever, swelling, skin rash, joint pains and swelling of the glands in the neck armpit or groin, anytime up to two weeks after the injection.

These may be serious side effects. You may need urgent medical attention.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storing Stonefish Antivenom

Stonefish Antivenom is usually stored in a doctor's surgery, hospital or ambulance. However, if you need to store it:

- Keep it where children cannot reach it.
- Keep it in the original pack until it is needed.
- Keep it in the refrigerator, between 2°C and 8°C and protect it from light. Do not freeze Stonefish Antivenom.

Do not use Stonefish Antivenom after the expiry date printed on the pack.

Do not use Stonefish Antivenom if the packaging is torn or shows signs of tampering.

Product description

What it looks like

Stonefish Antivenom is supplied in a vial.

Ingredients

Active ingredient:

- 2,000 units of Stonefish Antivenom. Other ingredients:
- sodium chloride
- phenol
- substances in horse blood.

Name and Address of Sponsor

Stonefish Antivenom is sponsored by: Seqirus Pty Ltd, ABN 26 160 735 035 63 Poplar Road Parkville 3052 Victoria Australia The Australian Registration Number is AUST R 74892.

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