Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sea Snake 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 Sea Snake 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 Sea Snake Antivenom is used for

What it is used for

Sea Snake Antivenom is given to those people who become ill after being bitten by sea snake.

Not everyone who is bitten needs the antivenom as some people have only very mild affects from the bite or none at all. However, some people can become very ill after being bitten, and in these people it is essential to use an appropriate amount of antivenom to counteract the effects of the poison.

How it works

Sea Snake Antivenom is an injection designed to help neutralise the effect of the poison (venom) of the sea snake.

It is made by immunising horses against the venom of the sea snake 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 being bitten by a sea snake.

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

Before you are given Sea Snake 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 bite.

However as Sea Snake Antivenom can be an emergency life-saving product, 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 received injections containing 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 Sea Snake Antivenom.

How Sea Snake Antivenom is given

How much is given

The dose for both adults and children is one vial (1,000 units). The dose 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 diluted and given slowly as a drip into a vein.

Once diluted Sea Snake Antivenom should be used immediately. Diluted antivenom should not be stored.

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

After having Sea Snake 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 Sea Snake 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 or pharmacist if you notice any of the following and they worry you:

- local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars
- chills
- aching muscles, muscle tenderness or weakness, not caused by exercise

- stomach pain or discomfort
- headache
- · nausea, vomiting and diarrhoea.

These side effects are usually mild.

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
- · chest pain
- · high temperature.

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 Sea Snake Antivenom

Sea Snake 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 Sea Snake Antivenom.

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

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

Product description

What it looks like

Sea Snake Antivenom is supplied in a vial. *Ingredients*

Active ingredient:

- 1,000 units of Sea Snake Antivenom.
- Other ingredients:
- · sodium chloride
- phenol
- water for injections.

This product also contains substances from horse blood.

Sea Snake Antivenom and its packaging components do not contain natural rubber latex.

Name and Address of Sponsor

Sea Snake 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 74901.

This leaflet was prepared in July 2019