

## Product Information

### **NAME OF THE MEDICINE**

SEA SNAKE ANTIVENOM

AUST R 74901

### **DESCRIPTION**

SEA SNAKE ANTIVENOM is prepared from the plasma of horses immunised with the venom of the sea snake *Enhydrina schistosa*. Each vial contains 1,000 units of antivenom. The product also contains phenol, sodium chloride and other equine plasma proteins in an aqueous solution. SEA SNAKE ANTIVENOM has been shown to be effective not only against the venom of *Enhydrina schistosa* but, to a varying degree, against the venoms of a wide variety of sea snakes present in northern Australian waters.

### **PHARMACOLOGY**

Sea snakes are abundant throughout the warmer waters of the Indian and Pacific oceans. They require a sea temperature of at least 20°C and are therefore common in Australian tropical waters although there has been one confirmed sea snake bite at a Sydney beach.

The venom of the sea snake is very potent but in many cases of human bites, little venom is injected. In a study of 101 cases in Malaysia, only 22% of bites were considered to be serious. However, 6 of the 11 who were seriously envenomed died before antivenom was available and 2 of 11 after introduction of the antivenom.

Sea snake bites can occur from inadvertently standing on the snake or, more commonly, they occur as an occupational hazard to fishermen sorting fish in their nets. The venom of the sea snakes contains potent neurotoxins that can cause muscle paralysis and respiratory failure leading to death. The venom also has myolytic properties. The muscle destruction can cause myalgia and renal failure. Hyperkalaemia can be severe. Myolysis has been demonstrated in monkeys with considerable elevation of creatine kinase levels. There is also elevation of aspartate transaminase (AST) levels in humans.

As there is considerable similarity between the toxins of the sea snakes and the Australian elapids, TIGER SNAKE ANTIVENOM is often effective in cases of sea snake envenoming and may be used if SEA SNAKE ANTIVENOM is not available.

### **INDICATIONS**

For the treatment of patients who exhibit manifestations of systemic envenoming following a bite by a sea snake.

### **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 SEA SNAKE 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.**

Most cases of sea snake bites are painless with no local swelling. A row of small teeth marks may be seen. Intense pain from underwater trauma is more likely to be due to a fish than a sea snake.

Up to two thirds of those bitten by a sea snake have little or no effect from the bite. Severely envenomed patients often develop symptoms soon after the bite, but in some, the potentially dangerous effects may be delayed for several hours. It is therefore essential to observe all those who have been bitten by a sea snake for at least 12 hours, prior to discharge. Such patients must be regularly monitored for signs of neuromuscular impairment, coagulopathy, myolysis, renal impairment and other abnormalities.

If the limb has been immobilised and a firm bandage applied, removal of the bandage and splint may precipitate the systemic effects of the venom. The bandage and splint should not be removed until the patient is in hospital with appropriate antivenom treatment available. As immobilisation causes local retention of the venom, the requisite period of observation of the patient for a minimum of 12 hours commences when the splint and bandage are removed.

**Severe cases of systemic envenoming should be managed in an intensive care unit, if possible and always in a setting where resuscitation facilities are immediately available.**

**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 may be more likely to occur in those who are atopic or 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 skin testing to determine patients who may have an allergic reaction are not satisfactory and should not be undertaken.

**Antivenoms may bind complement and produce an anaphylactoid reaction in patients who have had no previous contact with equine protein. The risk of such a reaction can be reduced by adequate dilution of the antivenom prior to infusion, although care should be taken to avoid fluid overload (see also DOSAGE AND ADMINISTRATION).**

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.

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 a similar animal 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..

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

### **Use in pregnancy**

There is no information on the safety of this 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 all Seqirus snake antivenoms. Adverse event frequencies are defined as follows:

Very common:  $\geq 1/10$ ; common:  $\geq 1/100$  and  $< 1/10$ ; uncommon:  $\geq 1/1000$  and  $< 1/100$ ; rare:  $\geq 1/10,000$  and  $< 1/1000$ ; and very rare:  $< 1/10,000$ .

### **Immune system disorders**

*Common:* Allergic reactions including anaphylactic shock and delayed serum sickness

### **Nervous system disorders**

*Common:* Headache

### **Gastrointestinal disorders**

*Uncommon:* Abdominal pain, vomiting, nausea and diarrhoea

### **Skin and subcutaneous tissue disorders**

*Common:* Urticaria, rash

### **Musculoskeletal and connective tissue disorders**

*Uncommon:* Myalgia

### **General disorders and administration site conditions**

*Common:* Pyrexia, chills

*Uncommon:* Local injection site reactions, chest pain

## **DOSAGE AND ADMINISTRATION**

A large proportion of people bitten by sea snakes have minimal or no effects from the bite and antivenom is unnecessary. When there is evidence of systemic envenoming from a sea snake, the contents of one vial (1,000 units) should be administered slowly by intravenous infusion after dilution with Hartmann's Solution or normal saline. Once diluted, SEA SNAKE ANTIVENOM should be used immediately. Do not store diluted antivenom.

The dose is the same for adults and children. The antivenom should be diluted 1 in 10, although a dilution of 1 in 5 may be more appropriate to avoid fluid overload in patients that are at risk (e.g. small children). Seek expert advice, regarding dilution of antivenom to avoid fluid overload, as required.

In cases of severe envenoming, when myalgia, muscle weakness, trismus, ptosis and ophthalmoplegia are present, an initial dose of 3,000 to 4,000 units should be given and up to 10,000 units may be required altogether. In less severe cases a total of 3,000 units will control most patients.

In the past, some authorities have advocated premedication with 0.25 mL of 1:1000 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).

**If the patient has the affected limb immobilised, the splint and pressure bandage should not be removed until the patient is in a unit where full resuscitation measures and antivenom are available.**

**Severe cases of systemic envenoming should be managed in an intensive care unit if possible and always in a setting where resuscitation facilities are immediately available.**

The patient must be monitored for at least 6 hours after the conclusion of the antivenom infusion.

**Before starting the infusion of antivenom, adrenaline should be prepared ready for 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.

SEA SNAKE 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:** SEA SNAKE ANTIVENOM is a concentrated injection for intravenous use available as vials containing 1,000 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:** SEA SNAKE ANTIVENOM should be protected from light and stored between 2 and 8°C. Do not freeze.

## **NAME AND ADDRESS OF THE SPONSOR**

Seqirus Pty Ltd  
63 Poplar Road  
Parkville Victoria 3052  
Australia

## **POISON SCHEDULE OF THE MEDICINE**

Prescription Only Medicine (S4)

**Date of first inclusion in the Australian Register of Therapeutic Goods:** 21 July 2000

**Date of most recent amendment:** 21 November 2017