

---

## Product Information

### NAME OF THE MEDICINE

FUNNEL WEB SPIDER ANTIVENOM

AUST R 31847

### DESCRIPTION

FUNNEL WEB SPIDER ANTIVENOM is prepared from the plasma of rabbits immunised with the venom of the male Sydney funnel web spider (*Atrax robustus*). Each vial of the product contains 125 units of antivenom which has been standardised to neutralise 1.25 mg of funnel web spider venom. The product also contains glycine, other rabbit plasma proteins, sodium chloride, sodium phosphate – dibasic and sodium phosphate – monobasic. It is presented as a freeze dried powder for reconstitution.

### PHARMACOLOGY

FUNNEL WEB SPIDER ANTIVENOM is a purified immunoglobulin (mainly immunoglobulin G), derived from rabbit plasma, which contains specific antibodies against the toxic substances in the venom of the Sydney funnel web spider, *Atrax robustus*.

There is evidence to show that the antivenom is effective in the treatment of patients bitten by some other funnel web spiders of the *Hadronyche* genus.

### INDICATIONS

For the treatment of patients who exhibit manifestations of systemic envenoming following a bite by a funnel web spider.

### 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 FUNNEL WEB SPIDER 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.**

**If the patient has received effective first aid (firm bandaging and a splint), symptoms and signs of envenoming may not become apparent until removal of the bandage but may then develop rapidly.**

**Removal of the bandage and splint may precipitate the systemic effects of the venom in patients who have been bitten.**

These typically consist of severe local pain, nausea, vomiting, abdominal pain, profuse sweating, salivation, lachrymation and severe dyspnoea. Mental confusion leading to coma may occur as well as hypertension and pulmonary oedema. Local and general fasciculation of muscles is usually present.

A proportion of people bitten by funnel web spiders have symptoms that are so mild that antivenom is not necessary.

The patient should be observed for signs of envenoming for at least four hours after being bitten or after removing the pressure bandage before a decision is made not to administer the antivenom.

As systemic effects of the venom can occur rapidly it may be necessary to urgently commence appropriate treatment, including antivenom administration.

**As this product is prepared from animal serum, severe allergic reactions may follow, including anaphylactic shock, though this is uncommon. Adrenaline must be available during antivenom therapy and prepared ready for use prior to antivenom administration.** Anaphylactoid reactions are more likely to occur in those who are atopic or who have previously received rabbit serum.

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.

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 envenomation and anaphylaxis.

Severe cases of systemic envenoming should be managed in an intensive care unit.

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 should be advised of the symptoms of serum sickness and warned to seek urgent medical attention if such symptoms develop.

#### **Use in pregnancy**

There is no information of the use 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 the 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 FUNNEL WEB SPIDER ANTIVENOM. 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

**Skin and subcutaneous tissue disorders**

*Common:* Urticaria, rash

**DOSAGE AND ADMINISTRATION**

The dose of FUNNEL WEB SPIDER ANTIVENOM is dependent on the extent of envenoming. The recommended initial dose is 2 vials of FUNNEL WEB SPIDER ANTIVENOM. Each vial is reconstituted with 10 mL of Water for Injections BP. Gently swirl to ensure the product is fully dissolved; the vial may be inverted to assist dissolution. A clear to slightly opalescent colourless solution is typically obtained within 10 minutes. After complete dissolution the product must be used immediately. FUNNEL WEB SPIDER ANTIVENOM should be administered by slow intravenous injection.

The dose is the same for both adults and children.

**Before giving the injection of antivenom, adrenaline should be prepared ready to use, as anaphylactic reactions can occur rapidly (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.**

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

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

If the effects of the venom have not been completely reversed, the dose of antivenom may be repeated in 15 minutes, providing it is safe to do so. In a few cases, further doses may be needed.

A proportion of people bitten by funnel web spiders have symptoms that are so mild that antivenom is not necessary. It is estimated that the proportion of those bitten by funnel web spiders who become seriously ill is between 1 in 5 and 1 in 10. First aid with pressure bandaging and immobilisation tends to delay the onset of the illness and may allow local detoxification. **Removal of the bandage may precipitate the onset of symptoms and signs of envenoming.**

The patient should be observed for signs of envenoming for at least four hours after being bitten or after removing the pressure bandage before a decision is made not to administer the antivenom.

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.

FUNNEL WEB SPIDER 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:** FUNNEL WEB SPIDER ANTIVENOM is available as a freeze dried preparation containing 125 units of antivenom as approximately 100mg immunoglobulin dispensed in 20mL glass containers.

**Storage Conditions:** FUNNEL WEB SPIDER ANTIVENOM should be protected from light and stored below 8°C (Refrigerate). The reconstituted product must be used immediately.

**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:** 4 November 1991

**Date of most recent amendment:** 23 December 2016