AUSTRALIAN PRODUCT INFORMATION – FUNNEL WEB SPIDER ANTIVENOM Powder for injection

1 NAME OF THE MEDICINE

Funnel web spider antivenom (rabbit) as active ingredient

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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 as approximately 100mg immunoglobulin which has been standardised to neutralise 1.25 mg of funnel web spider venom. Once reconstituted, the product also contains 81 mg glycine, 69 mg sodium chloride, 9 mg dibasic sodium phosphate and 3 mg monobasic sodium phosphate dihydrate per vial. Each vial contains ≤ 810 mg of plasma protein of rabbit origin.

3 PHARMACEUTICAL FORM

FUNNEL WEB SPIDER ANTIVENOM is a freeze dried powder for reconstitution for intravenous injection (125U). Pre-reconstitution it is a white, freeze dried powder in a glass vial. Post-reconstitution it is a clear to slightly opalescent, colourless solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

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

4.2 DOSE AND METHOD OF 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 SECTION 4.2 – DOSE AND METHOD OF ADMINISTRATION).

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 in one patient on one occasion only and discard any residue.

4.3 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 **SECTION 4.4 – SPECIAL WARNINGS AND PRECAUTIONS FOR USE** for use of FUNNEL WEB SPIDER ANTIVENOM in patients with a known allergy.)

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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 the elderly

No data available

Paediatric use

See **SECTION 4.2 – DOSE AND METHOD OF ADMINISTRATION** .

Effects on laboratory tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The following adverse reactions, presented below according to System Organ Class and frequency, have been identified during post approval use of FUNNEL WEB SPIDER ANTIVENOM. 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

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems

4.9 OVERDOSAGE

For information on the management of overdose, contact the Poisons Information Centre on 131 126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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.

Clinical trials

No data available

5.2 PHARMACOKINETIC PROPERTIES

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available

Carcinogenicity

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Refer to **SECTION 2 – QUALITATIVE AND QUANTITATIVE COMPOSITION**.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

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

6.5 NATURE AND CONTENTS OF CONTAINER

FUNNEL WEB SPIDER ANTIVENOM is supplied in a single clear glass vial.

The vial and all associated components do not contain natural rubber latex.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Not applicable.

7 MEDICINE SCHEDULE (POISONS STANDARD)

Prescription Only Medicine (S4)

8 SPONSOR

Seqirus Pty Ltd
ABN: 26 160 735 035
63 Poplar Road
Parkville Victoria 3052
Australia

9 DATE OF FIRST APPROVAL

4 November 1991

10 DATE OF REVISION

20 August 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Updated as per TGA Form for providing PI dated March 2018.