AUSTRALIAN PRODUCT INFORMATION – RED BACK SPIDER ANTIVENOM Solution for Injection

1 NAME OF THE MEDICINE

Red-back Spider Antivenom (equine) as active ingredient.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

RED BACK SPIDER ANTIVENOM is prepared from the plasma of horses immunised with the venom of the female red back spider *(Latrodectus hasselti*). Each vial contains 500 units of antivenom which has been standardised to neutralise 5 mg of venom. Each 1 mL of product also contains 2.2 mg phenol, 8 mg sodium chloride and water for injections to 1 mL. Each vial contains ≤ 100 mg per mL of plasma protein of equine origin. The product volume is potency dependant thus it varies from batch to batch. Please refer to the product volume printed on the carton.

3 PHARMACEUTICAL FORM

RED BACK SPIDER ANTIVENOM (500U) is a solution for injection available as vials containing 500 units of antivenom in aqueous solution. It is a colourless to light straw coloured, slightly viscous, transparent solution in a vial.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the treatment of patients who exhibit manifestations of systemic envenoming following a bite by a red back spider (*Latrodectus hasselti*).

4.2 DOSE AND METHOD OF ADMINISTRATION

A large proportion of people bitten by red back spiders have symptoms that are so mild that antivenom is not necessary. When there is evidence of severe local and/or systemic envenoming by a red back spider, the contents of one vial (500 units) should be given intramuscularly. The dose is the same for both adults and children.

In cases of life threatening envenoming, the intravenous route may be used. The antivenom is first diluted 1:10 in Hartmann's Solution or 0.9% w/v Sodium Chloride. Seek expert advice regarding dilution of antivenom to avoid fluid overload, as required. **NOTE: The intravenous route is more likely to precipitate anaphylactoid reactions.**

If the effects of the venom have not been completely reversed in two hours, a second injection of antivenom may be necessary providing it is safe to do so. In a few cases further doses may be needed as symptoms of envenoming can sometimes last for long periods after the bite. It is unusual to require more than three vials of antivenom. If after three vials there has been no improvement in symptomatology, consider the possibility the bite was not by a red back spider. It may occasionally be necessary to treat both envenoming and anaphylaxis simultaneously.

Before giving the injection of antivenom, adrenaline should be prepared ready for use, as anaphylactic reactions can occur rapidly (see SECTION 4.4 – SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

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.

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.

RED BACK 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 RED BACK 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.

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 horse serum. This would include patients who received Tetanus Antitoxin prior to 1974. 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 initial skin testing are not satisfactory and should not be undertaken.

Should anaphylaxis occur, suspend administration of antivenom and implement treatment measures 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.

Severe cases of systemic envenoming should be managed in an intensive care unit. Although the local effects of envenoming (severe pain, erythema, swelling and sweating) may occur in the first hour, severe systemic effects may not occur until 12 hours after the bite.

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.

The incidence of serum sickness is greater with larger volumes of antivenom, but can be expected to occur in at least 5% of patients receiving horse serum for the first time.

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 limited, but inconclusive information on the use of the 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 Seqirus RED BACK 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.

Blood and lymphatic system disorders
Rare: Lymphadenopathy

Immune system disorders
Common: Allergic reactions including anaphylactic shock and delayed serum sickness

Skin and subcutaneous tissue disorders
Uncommon: Urticaria, rash

General disorders and administration site conditions
Uncommon: Local injection site reactions
Rare: Pyrexia, chest pain

4.9 OVERDOSE

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

RED BACK SPIDER ANTIVENOM is a concentrated solution of purified globulins derived from horse plasma, which contains specific antibodies against the toxic substances in the venom of the red back spider (*Latrodectus hasselti*).

The effects of the venom, particularly severe pain, may persist for days or even weeks and there are reports of satisfactory use of the antivenom to alleviate these symptoms up to 10 days after a confirmed red back spider bite.

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

RED BACK SPIDER ANTIVENOM should be protected from light and stored at 2-8°C. Do not freeze.

6.5 NATURE AND CONTENTS OF CONTAINER

RED BACK SPIDER ANTIVENOM is available 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

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Australia

9 DATE OF FIRST APPROVAL

21 July 2000

10 DATE OF REVISION

23 August 2019

SUMMARY TABLE OF CHANGES

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