

ViperaTAB®

Affinity Purified, European Viper Antivenom (Ovine Fab for Injection)

Presentation: Package contains two vials of ViperaTAB sterile white or off-white friable cake. Each vial of ViperaTAB contains 100 mg of antigen binding fragments (Fab) derived from antibodies raised in sheep immunised with the venom of *Vipera berus*, the European adder.

Potency: Upon reconstitution with Sterile Water for Injection (5 mL per vial) each mL of ViperaTAB will neutralise not less than 50 mouse LD₅₀ of *V berus* venom. Although vials may contain up to 500 mouse LD₅₀ neutralising units the minimum potency specification is 250 mouse LD₅₀ neutralising units per vial.

Indication: ViperaTAB is indicated for the treatment of moderate or severe envenoming by *V berus*. Whilst animal data suggests that the antivenom may be of value in the treatment of envenomation by related snakes, namely *Vipera aspis* and *Vipera ammodytes*, this has not been confirmed to date in humans. Protherics UK Limited make no claims for the effectiveness of the product for treating *V aspis* or *V ammodytes* envenomation.

Dosage and administration: Two vials of ViperaTAB should be reconstituted, each with 5 mL of Sterile Water for Injection, to give a clear to slightly opalescent solution, essentially free from particulate matter. Reconstituted product should be used promptly. The reconstituted liquid contents of two vials (total 200 mg) should be aseptically injected into an infusion bag containing 100 mL of isotonic saline and given by single dose i.v. infusion over 30 min. Additional doses of two vials (200 mg) should be administered in a similar manner if and when there is clinical evidence of progression of signs and symptoms of envenomation.

Supportive and adjunctive therapy: The wound should be cleaned with antiseptic and covered with a non-occlusive dry sterile dressing. The bitten extremity should be placed in the most comfortable position. Hypovolaemia may require the administration of intravenous fluids and plasma. Severe anaemia may require blood transfusion. Anti-tetanus agents are indicated. Analgesics may be administered for pain; however, aspirin and other antiplatelet drugs should be avoided. Epinephrine, antihistamines and corticosteroids are indicated when there are anaphylactoid venom or antivenom reactions (urticaria, angio-oedema, hypotension and bronchospasm). If the bite is on the face or neck, progressive oedema is apt to compromise the airway: in such cases, early administration of antivenom and close attention to airway maintenance may be life-saving.

Precautions: Since the Fab fragment of the antibody lacks the antigenic determinants of the Fc fragment, it should pose less of an immunogenic threat to patients than does an intact immunoglobulin molecule. Clinical experience with other Fab fragment antivenom products suggests that anaphylactoid reactions can occur and are related to the amount and rate of Fab administration. These reactions are temporal, self-limiting and non life-threatening and may include, but are not limited to, mild urticaria, wheezing, flushing and skin rash. Prior to administration, appropriate therapy should be prepared, including 1: 1000 adrenaline injection; an airway; oxygen; chlorpheniramine maleate (adults: 10 mg intravenously; children: 0.2 mg/kg intravenously); a corticosteroid and a plasma expander. An intravenous drip should be in place to administer other drugs if needed but adrenaline should only be given subcutaneously or intramuscularly. Constant attendance and observation of the patient for untoward reactions is required during and for at least one hour after administration of the antivenom.

Storage conditions: This product should be stored at 2° to 8°C (36° to 46°F)

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