

## ViperaTAB®

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

**Presentation:** Each package contains two vials of ViperaTAB with each vial containing 100 mg of antigen binding fragments (Fab) in 4mL of 20mM sodium acetate buffer, pH 4.0. Fab fragments were derived from antibodies raised in sheep immunised with the venom of *Vipera berus*, the European adder.

**Pharmaceutical form:** Concentrate for solution for infusion

**Potency:** Each mL of ViperaTAB will neutralise not less than 100 mouse LD<sub>50</sub> of *V. berus* venom. Although vials may contain in excess of 5000 mouse LD<sub>50</sub> neutralising units, the minimum potency specification is 400 mouse LD<sub>50</sub> 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 by data in humans. MicroPharm Ltd makes no claims for the effectiveness of the product for treating *V. aspis* or *V. ammodytes* envenomation.

**Dosage and administration:** The liquid contents of two vials (total 8mL containing 200mg Fab fragments) should be aseptically injected into an infusion bag containing 100mL of isotonic saline and given by a single dose intravenous infusion over 30 minutes. Additional doses of two vials should be administered in a similar manner if signs and symptoms of envenomation are either not alleviated or recur.

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

### Precautions:

#### General

ViperaTAB may contain mercury in the form of ethyl mercury from thiomersal, used in the manufacturing process. The final product contains less than 10µg of mercury per vial, which amounts to no more than 20µg of mercury per dose (based on a dose of 2 vials). While there are no definitive data on the toxicity of ethyl mercury, literature suggests that information related to methyl mercury toxicity may be applicable. Some patients may experience an allergic reaction to thiomersal and should inform their doctor if they have any known allergies.

#### Anaphylaxis, Anaphylactoid, and Allergic Reactions

Since the Fab fragment of the antibody lacks the antigenic determinants of the Fc fragment, it poses less of an immunogenic threat to patients than does an intact immunoglobulin molecule. Clinical experience with other Fab fragment products suggests that anaphylactoid reactions are rare but 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 of antivenom, appropriate therapy should be prepared. This may include 1:1000 adrenaline injection; an airway; oxygen; chlorpheniramine maleate (adults: 10mg intravenously; children: 0.2mg/kg intravenously); a corticosteroid or 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 an hour after the administration of the antivenom.

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

**Manufactured by:** MicroPharm Ltd, Station Road Industrial Estate, Newcastle Emlyn, SA38 9BY, United Kingdom

#### Distribution:

Sweden, Finland, Norway, Denmark, Iceland, Estonia, Latvia, Lithuania and Germany:  
Swedish Orphan Biovitrum International AB, SE-112 76 Stockholm, Sweden  
Tel +46 (0) 8 697 20 00 Fax +46 (0) 8 697 23 30

#### Rest of Europe:

Flynn Pharm Ltd, Hertlands House, Primett Road, Stevenage, Hertfordshire, SG1 3EE, UK  
Tel +44 (0) 1438 727822 Fax +44 (0) 1438 727805

For supply on a named patient basis only

This is an unlicensed medicine

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