ViperaTAb®

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

Presentation

ViperaTAb is a concentrate for infusion.

Each package contains two ampoules of ViperaTAb with each ampoule containing 100 milligram (mg) of antigen binding fragments (Fab) in 4 millilitres (mL) of 20 millimolar 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.

Store at 2 to 8°C. Do not use after the designated expiry date.

Potency

The active ingredient of ViperaTAb is sheep antivenom immunoglobulin fragments. Each 4mL of ViperaTAb will neutralise not less than 500 mouse LD_{50} of *Vipera berus* venom.

Indication

ViperaTAb is indicated for the treatment of moderate or severe envenoming by *Vipera 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 *Vipera aspis* or *Vipera ammodytes* envenomation.

Dosage and Administration

Aseptically inject the liquid contents of two ampoules (total of 8mL containing 200mg Fab fragments) into an infusion bag containing 100mL of isotonic saline. Administer as a single dose intravenous infusion over 30 minutes. If signs and symptoms of envenomation are either not alleviated or recur, administer additional doses of two ampoules in a similar manner.

Supportive and Adjunctive Therapy

Clean the wound at the bite site with antiseptic and cover with a non-occlusive dry sterile dressing. Place the bitten extremity in the most comfortable position. Administer intravenous fluids if hypovolaemia occurs. Severe anaemia (from blood loss) may require blood transfusion. Anti-tetanus agents may be indicated. Administer analgesics for pain. Avoid aspirin and other anti-platelet drugs. 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.

General Precautions

ViperaTAb may contain mercury in the form of ethyl mercury from thiomersal, used in the manufacturing process. The final product contains less than 5 microgram (µg) of mercury per ampoule, which amounts to no more than 10µg of mercury per dose (based on a dose of 2 ampoules). 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 temporary, self-limiting, and non-life-threatening. They 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)

Manufacturer

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All medical information and safety related enquiries regarding ViperaTAb ® should be addressed to:

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For supply on a named patient basis only

This is an unlicensed medicine

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