

Snake Antivenom for Sub – Sharan Africa EchiTAbG™

Product Overview

Type: Snake Antivenom for Sub-Sharan Africa

Commercial Name:EchiTAbG™Manufacturer:MicroPharm LtdCountry:Wales, UK.

URL: https://micropharm.co.uk/

Responsible NRA: Medicines and Health Products Regulatory Agency (MHRA)

Country: United Kingdom

URL: https://www.gov.uk/government/organisations/medicines-and-

healthcare-products-regulatory-agency

WHO Recommendation

Effective date: 20/06/2019

Product Description:

Pharmaceutical Form: Liquid: ready to use

Presentation:AmpouleNumber of Doses:1 (10 mL)Route of administration:IntravenousShelf Life:12 monthsStorage temperature:2°C to 8°C

Immunoglobulins content: 250 mg/ampoule

Packaging configuration: Box containing 5 ampoules (5 doses) [Dimensions: 7.6 x 5.1 cm]

This product can be used for the treatment of envenoming by the following species of snakes:

Common Name	Species Name	Countries of Occurrence
West African Carpet viper	Echis ocellatus	Benin, Burkina Faso, Cameroon, Central African Republic (west), Chad, Côte d'Ivoire, Ghana, Mali, Niger, Nigeria, Togo.
East African Carpet viper	Echis pyramidum	Central African Republic (north-east), Egypt, Eritrea, Ethiopia, Djibouti, Kenya, South Sudan, Sudan, Uganda.

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EchiTAbG®

Echis ocellatus Antivenom, Ovine IgG for Injection

Name of drug: EchiTAbG

Presentation: Package contains five ampoules (10 mL each) of EchiTAbG sterile injection. Each ampoule contains a minimum of 230 mg of immunoglobulins purified from antisera of sheep immunised with the venom of *Echis ocellatus*, the West African saw-scaled or carpet viper, and formulated in citrate-buffered saline.

Potency: Each ampoule of EchiTAbG contains a minimum of 35 mg specific antibody.

Indication: EchiTAbG is a monospecific antivenom indicated for the treatment of systemic envenoming caused by the bite of the West African saw-scaled or carpet viper, *E. ocellatus*, as shown by the presence of incoagulable blood or prolonged clotting time or spontaneous systemic bleeding (for example from the gums or nose). No claim is made for the effectiveness of the product for treating envenoming by any other species of snake, including other species of *Echis*.

Dosage and administration: The recommended initial treatment dose is one ampoule of EchiTAbG. The contents of one ampoule should be administered by slow intravenous injection over not less than 10 minutes. Further ampoules can be given by the attending physician if indicated clinically, for example if the blood remains incoagulable six hours or longer after the initial dose.

Supportive and adjunctive therapy: The wound at the site of bite 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. Severe anaemia (from blood loss) may require transfusion with whole safe blood. Anti-tetanus agents are indicated. Analgesics such as paracetamol or codeine phosphate may be administered for pain; however, aspirin and other anti-platelet drugs should be avoided. The treatment of anaphylactic reactions (urticaria, angio-oedema, hypotension and bronchospasm) is adrenaline, an antihistamine, and a corticosteroid (doses below). 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.

Contraindications: There are no contraindications to EchiTAbG.

Precautions: Clinical experience with antivenoms suggests that anaphylactic reactions can occur and are related to the amount and rate of administration of the product. These reactions are usually temporary, self-limiting, and non-life-threatening. They may include, but are not limited to, itching, mild urticaria, flushing, faintness, nausea/vomiting, angio-oedema, and wheezing.

Appropriate treatment for anaphylactic reactions must be available prior to administration of EchiTAbG, particularly 1:1000 adrenaline (epinephrine) by intramuscular injection (adult dose 0.5ml; child more than 12 years, 500 micrograms (0.5 ml); 6–12 years, 300 micrograms IM (0.3 ml); less than 6 years, 150 micrograms IM (0.15 ml). An airway; oxygen; chlorphenamine maleate (adults 10 mg intravenously; children 0.2 mg/kg intravenously); a corticosteroid for intravenous injection; and a plasma expander may also be needed. An intravenous drip should be in place to administer fluids, and drugs if necessary, but adrenaline should only be given intramuscularly.

In high-risk patients, pre-treat with adrenaline 1:1000 (0.1%) (adults and children 6 years or older 0.25 ml; less than 6 years 0.15 ml) by subcutaneous injection and an antihistamine and a corticosteroid (both intravenously).

Constant attendance and observation of the patient for untoward reactions is required during and for at least one hour after the administration of the antivenom.

Storage conditions: Store at 2 - 8 °C. Do not freeze.

Produced by: MicroPharm Ltd., Wales, SA38 9BY, United Kingdom (licence number MIA 8794), in collaboration with the EchiTAb Study Group (Nigeria)

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