For the use of Registered Medical Practitioner or a Hospital or a Laboratory

NAJA PHILIPPINENSIS VENOM + NAJA SAMARENSIS VENOM + OPHIOPHAGUS HANNAH VENOM ANTI-SERUM

TARADOC

Lyophilized Powder for Injection (I.V.)
ANTIVENOM
(Polyvalent, Enzyme Refined,
Equine Antivenom Immunoglobulin Fragments)

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FORMULATION:
Each mL upon reconstitution with 10 mL Sterile Water for Injection neutralizes snake venoms of the following :
0.45 mg *Naja philippinensis* venom
0.60 mg *Naja samarensis* venom
0.60 mg *Ophiophagus hannah* venom
Preservative: Cresol B.P. ≤ 0.25% v/v
Stabilizer: Glycine B.P.
Excipient: Sodium Chloride B.P.

DESCRIPTION:
Taradoc is prepared from purified plasma of healthy horses, which have been hyperimmunized against venoms of the most dangerous snakes mentioned above. The antiserum is purified from whole equine immune serum by pepsin digestion, controlled heating and caprylic acid precipitation and ultra-filtration followed by sterile filtration.

INDICATIONS:
Taradoc is indicated for the treatment of envenomation by *Naja philippinensis, Naja samarensis, Ophiophagus Hannah* snake species in patients rapidly spreading edema or systemic signs: vomting, diarhea, abdominal pain and hypotension.

RECONSTITUTION:
The freeze dried antiserum powder is reconstituted with 10 mL of Sterile Water for Injection B.P. is supplied with this pack. Withdraw the diluent in a sterile syringe.
Insert the needle through the stopper of the vial containing anti venom and point the diluent jet to the center of lyophilized pellet of antivenom to the dissolved in order to prevent floating. Swirl the vial gently for one to three minutes and do not shake to avoid foaming.

DOSAGE AND ADMINISTRATION:
Reconstituted antivenom is administered as soon as possible if clear-cut signs/symptoms of envenomation are evident. It can be administered in two ways.

1. Intravenous injections: Reconstituted antivenom is administered by slow intravenous injection (1-2 mL/minute).
2. Infusion: Reconstituted antivenom is diluted in isotonic saline or glucose solution, 5-10 mL/Kg body weight.

At present there is no simple method to measure the amount of circulating venom in the body, therefore the antivenom dose cannot be accurately recommended. The dose also depends on the type of snake bite and severity of envenomation. In consideration to the requirement of venom quick neutralisation, two vials are usually injected directly by I.V. route slowly i.e. 1-2 mL/minute (taking care of sensitivity reaction). Two more vials are given after half an hour to one hour, if the symptoms of envenomation persist. This way patient should be given doses (further dose can be given with intravenous fluid) till the envenomation symptoms subside.

The patient should be closely monitored for 2 hours. Local administration of antivenom in or around the bite site is ineffective, painful, and may raise the intra compartmental pressure, particularly in the digits i.e. fingers and toes, hence it is not recommended.

CONTRAINDICATIONS:
Relative contraindications in cases of known hypersensitivity to heterologus proteins of equine origin or to any excipients. The risk of life associated with envenomation outweighs any potential contraindications.

WARNINGS AND PRECAUTIONS:
The treatment must be administered in a hospital setting in order to be able to manage any immediate hypersensitivity reactions as soon they occur.
Given that the equine immunoglobulin antivenom for Taradoc is heterologus in nature, the risk of anaphylactic adverse reactions must always be evaluated.
In order to detect prior sensitization to heterologus proteins, the patient must be questioned systematically and in detail regarding their history of allergies, with a particular focus on previous injections of heterologus proteins that may (or may not) have triggered possible reactions.
Hypersensitivity to contact with animals particularly horses and even food allergies must also be determined.
In the event of sign intolerance, reduce the rate of infusion or stop it if necessary. The clinical signs of allergic or anaphylactic reaction can be mistaken for those of envenomation. If allergic or anaphylactic reactions occur, the infusion must be initiated immediately.
In the event of shock, treatment of the shock symptoms must initiate immediately. The infusion must always be started under close medical supervision, at a slow rate 15 drops/min or 50 ml/hour. This medicinal product contains Sodium. The level of sodium is less than 1 mmol per dosage unit, i.e. "sodium-free".

INTERACTIONS:
No interaction of equine immunoglobulin F(ab')2 fragments antivenom with other medicinal product has been reported.

PREGNANCY AND LACTATION:
The safety of the product during pregnancy has not been established by clinical trials in humans with Taradoc. In view of the fatal risk associated with envenomation, pregnancy does not constitute a contraindication to the set-up of the post-exposure antivenom treatment.
Always ask for your doctor's or pharmacist's advise before using a medicinal product.

SNAKEBITE MANIFESTATIONS:
In Snake bite, there is creeping paralysis of muscles of eyelids, staggering gait, difficulty in speaking, blurred vision and dropping of head, accompanied by nausea and vomiting. These symptoms are due to the predominance of neurotoxins. Death may result within minutes or several hours due to respiratory failure.

Antivenom Reaction
Anaphylaxis is life-threatening, but if the correct protocol is followed, it can be effectively treated and dealt with. Anaphylaxis can be of rapid onset, and can deteriorate into a life threatening emergency very quickly. The patient should be monitored closely, and at the first sign of any of the following, antivenom should be discontinued, and 0.5 mg of 1:1000 Adrenaline must be administered intramuscularly; urticaria, itching, fever, chills or rigor, nausea, vomiting, diarrhea, abdominal cramps, tachycardia, hypotension, bronchospasm and angioedema.
Children must be given 0.01 mg/kg body weight of adrenaline I.M.
In addition, to provide longer term protection against anaphylactoid reaction, 100 mg of Hydrocortisone and 10 mg of H antihistamine can be given I.V. The dose 2 for children is 0.2 mg/kg of antihistamine I.V. and 2 mg/kg of hydrocortisone I.V. If after 10 to 15 minutes, the patient's condition has not improved, or if the condition is worsening, the second dose of 0.5 mg of Adrenaline 1:1000 I.M. may be given. In the vast majority of cases, no more doses will be required. If there is hypotension or haemodynamic instability. I.V. fluids should be given. Once the patient has recovered, the antivenin can be restarted slowly for 10-15 minutes keeping the patient under close observation. Then the normal drip rate can be resumed. Serum sickness reactions sometimes occur.
But these usually take a few days to a week and can be easily treated with oral antihistamines and corticosteroids (for e.g., Prednisolone-adults 5 mg dose shall be administrated in 6 hours of time ; child 0.7 mg/kg/day).

Associated Treatment:
Snake bite can cause moderate to severe pain at the bite site. This normally responds well to paracetamol. Aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) should not be administered, as they can exacerbate bleeding. Mild opiates (such as tramadol 50 mg) can be administered, for severe pain.
Neostigmine is an anticholinesterase drug, which prolongs the action of acetylcholine, thereby reversing respiratory failure and neurotoxic symptoms. It is particularly effective in postsynaptic neurotoxins such as those of the Cobra.

Shelf Life:
Four years from the date of manufacturing for the lyophilized form.

STORAGE CONDITION:
Store the freeze dried preparation (below 30°C) and avoid exposure to excessive heat. Reconstituted liquid should not be stored for long nor should be allowed to freeze.

AVAILABILITY:
Taradoc is supplied as freeze dried powder in 10 mL USP Type -1 glass vial. 10 mL Sterile Water for Injection B.P. is supplied as diluent along with vial.

Disposal:
Left over product and used empty vials should be discarded as biomedical waste.

Caution: Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADR Reporting statement:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

For single use only.

Manufactured by:
VINS Bioproducts Limited
SY. No. 117, Thimmapur (V), Kothur (M),
Ranga Reddy (Dist.), Telangana State, India

Imported and Distributed by:
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