

For the Medical Profession

# DIPHTHERIA ANTITOXIN 10000 I.U. I.P/B.P.

## 10 mL

### Composition:

Each mL contains:

Enzyme refined, Equine Diphtheria antitoxic immunoglobulin fragments not less than 1000 I.U.

Preservative : Cresol I.P./B.P.  $\leq$  0.25% v/v

Excipients : Sodium Chloride I.P./B.P.

Stabilizer : Glycine I.P./B.P.

### Description:

Diphtheria antitoxin is prepared by hyperimmunising Equines with diphtheria toxin/toxoid. Plasma obtained from hyperimmunised Equines which is rich in antibodies to diphtheria toxin is enzyme refined, purified and concentrated. The antitoxin has specific capacity of neutralizing toxin secreted by *Corynebacterium diphtheriae*, the causative organism of diphtheria.

### Pharmacodynamic/Pharmacokinetics

Not applicable.

### Use in prophylaxis:

The use of diphtheria antitoxin is not recommended for prophylaxis as its protective effect is of short duration (1 to 2 weeks only) and furthermore, it may cause sensitization to horse sera. Instead, the contacts of diphtheria patients should receive a dose (0.5 mL) of adsorbed diphtheria vaccine (Diphtheria vaccine, adsorbed PTAP), or adsorbed diphtheria - tetanus vaccine, (D-T vaccine adsorbed PTAP, which protects against both diphtheria and tetanus) and followed after 1 to 2 months with the second dose. Prophylaxis with diphtheria vaccine gives protection for many years and is practically free from reaction.

### Use in treatment:

A dose of 10,000 to 30,000 I.U. of diphtheria antitoxin may be injected intramuscularly in mild to moderately severe cases of diphtheria and upto a maximum of 100,000 I.U. in severe cases after testing serum sensitivity (see below for reactions to horse serum). I.V. route is the preferred route of administration in severe cases. In that case Diphtheria Antitoxin is mixed in 250 to 500 mL of normal saline and administered over 2-4 hours. In addition, antibiotics & corticosteroids may be administered. It is advised that after recovery from diphtheria, patients should be actively immunised for long term protection by the use of two doses at an interval of 1 to 2 months with adsorbed diphtheria vaccine or with adsorbed diphtheria - tetanus vaccine.

### Reactions to Equine serum:

Injection of diphtheria antitoxin in horse-serum-sensitive individuals can produce immediate reaction of acute anaphylaxis which could sometimes be fatal unless immediately countered by

injecting 1 mL of 1:1000 adrenaline intramuscularly. Every care should be taken to prevent this reaction. Before injection of diphtheria antitoxin, it is necessary to enquire from the patient (1) whether he/she has had injections of any serum before, (2) whether there is personal or family history of allergy i.e. asthma, eczema or drug allergy. The sensitivity of the patient to serum is tested by injecting subcutaneously 0.1 mL of diphtheria antitoxin diluted 1:10 and the patient is observed for 30 minutes for local and general reactions. If the test dose shows either local reaction such as wheal and flare or general anaphylactic reaction such as pallor, sweating, nausea, vomiting, urticaria or fall of blood pressure these should be treated with 1 mL of 1:1000 adrenaline (which should always be kept handy) before injecting the main dose of diphtheria antitoxin. Half the dose of adrenaline may be repeated 15 minutes later if necessary.

### Dosage and Administration:

In allergic individuals Diphtheria antitoxin is to be injected 15 to 30 min. after administration of antihistamines such as injectable pheniramine maleate and injectable hydrocortisone intramuscularly. One mL of adrenaline (1:1000) may be injected intramuscularly at the same time as the antiserum. Administration of hydrocortisone or adrenaline may be repeated if necessary.

### Adverse Effects:

In some cases symptoms such as itching, urticaria rash, pains in joints and muscles, fever, enlargement of lymph glands appear 7-12 days after the injection of diphtheria antitoxin. These should be treated with antihistamines and corticosteroids. Usually these symptoms of serum sickness last a few days and the patients recover without any complications.

**Storage:** Store at a temperature between 2°C to 8°C in a refrigerator. Do not freeze.

**Presentation:** Vials containing 10000 I.U. (10 mL).

**Shelf Life:** Two years from the date of manufacturing.

**Disposal:** Left over Diphtheria Antitoxin 10000 I.U. and used empty vials should be discarded as biomedical waste.



Manufactured by:

**VINS BIOPRODUCTS LIMITED**

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