DIPHTHERIA ANTITOXIN I.P.

(For the use of only by a Registered Medical Practitioner or Hospital or Laboratory)

(LIQUID ENZYME REFINED EQUINE IMMUNOGLOBULINS)

COMPOSITION:

Each ml of Diphtheria Antitoxin contains not less than 1000 IU
Phenol (As preservative) NMT 0.25%w/v
Glycine : Stabilizer
Sodium Chloride: Excipient
Diphtheria Antitoxin, I.P. is a sterile solution containing enzyme refined Anti diphtheria equine immunoglobulin F(ab')2 fragments as a clear and colorless to yellowish liquid for parenteral administration. It is produced by pepsin digestion, heat inactivation at controlled temperature and caprylic acid precipitation of hyper immune plasma derived from healthy equines immunized with Diphtheria toxoid.

INDICATION:

Diphtheria Antitoxin I.P. gives passive immunity to persons having no or minimal immunity against the toxin formed by Corynebacterium diphtheriae, the causative organism of Diphtheria.

DOSAGE AND ADMINISTRATION :

Diphtheria Antitoxin (DAT) is recommended for treatment of Diphtheria and in rare circumstances, for prophylaxis in unimmunized persons who were exposed to Diphtheria. Diphtheria Antitoxin is given as soon as clinical evidence of diphtheria appears without waiting for bacterial isolation as patient condition may deteriorate rapidly. The therapeutic dose is determined by site & size of membrane formation, severity & duration of disease. Antibiotics can stop spread of bacteria and eliminate them, however, they cannot neutralize diphtheria toxin and hence not a replacement of antitoxin.

For prophylaxis - The use of DAT is generally 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. When it is considered necessary, the dose depends on time since exposure, clinical condition and the extent of exposure. Usually a dose of 5000 to 10000 I.U. is administered intramuscularly as a single dose to adults and children. In addition, the patient should receive active immunization by a dose diphtheria toxoid at different place along with antibiotics.

For treatment -

Route of administration-

The IV route is the preferred route of administration of DAT, especially in severe cases. The antitoxin dose should be mixed in 250 –500 mL of normal saline and administered slowly over 2 – 4 hours, closely monitoring for anaphylaxis. The antitoxin may be given IM in mild or moderate cases.

Temperature -

Antitoxin should be warmed to 32–34°C (90–95°F) before injection. Warming above the recommended temperature should be carefully avoided because the DAT proteins will denature.

Dosage-

Give the entire treatment dose of DAT by IV (or IM) in a single administration.
The recommended DAT treatment dosage ranges are:

Pediatric and Adult DAT Doses

Diphtheria clinical presentation	DAT dose (units)
Pharyngeal or laryngeal disease of 2 days duration	20,000 – 40,000
Nasopharyngeal disease	40,000 – 60,000
Extensive disease of 3 or more days duration, or any patient with diffuse swelling of neck	80,000 – 100,000
Skin lesions only (rare case where treatment is indicated)	20,000 – 40,000

Children should be given the same dose like adults. In addition, antibiotics & corticosteroids may be administered.

ADVERSE REACTIONS:

Diphtheria Antitoxin being derived from equines is heterologous to humans and hence the foreign proteins in the product can give occasional reaction such as pallor, sweating, nausea, vomiting, urticaria or fall of blood pressure, which could be countered immediately by injection of 1 ml. of 1:1000 adrenaline which should be always kept handy, before injecting the dose of Diphtheria Antitoxin. Every care should be taken to prevent these reactions. Before injection of Diphtheria Antitoxin it is necessary to enquire from the patient,
1) Whether the patient has had injections of any equine origin serum product previously.
2) Whether there is personal or family history of allergy, i. e. asthma, eczema or drug allergy.

In allergic individuals, the Diphtheria Antitoxin can be injected 15 to 30 min. after administration of antihistamines, Hydrocortisone intramuscularly and 1 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.

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

HOW IT IS SUPPLIED:

Diphtheria Antitoxin- 10,000 I.U. in 10 ml

STORAGE:

It should be stored at 2 °C to 8°C. Do not freeze and keep protected from heat.

CONTRAINDICATIONS AND PRECAUTIONS:

Proper precautions are necessary while dealing with persons with a known hypersensitivity to constituents of product. The predictability value and necessity of skin sensitivity test is controversial; however, it may be performed at the discretion of doctor as follows-
a.Inject 0.1 ml Diphtheria Antitoxin diluted 1:10 in physiological saline intra-dermally into the flexor surface of the forearm to raise a bleb of about 3-4 mm diameter.
b.Inject an equal amount of normal saline as a negative control on the flexor surface of the other forearm.
c.After 15 minutes an increase in diameter to > 10 mm of induration surrounded by flare is taken as positive skin test, provided the reaction on the saline test was negative.
d.An increase or abrupt fall in blood pressure, syncope, hurried breathing, palpitation and any other systemic manifestation should be taken as positive test.
A negative skin test must never assure physician that no anaphylactic reaction will occur.

Manufactured by
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Reference:

Use of Diphtheria Antitoxin (DAT) for Suspected Diphtheria Cases : Centers for Disease Control and Prevention (CDC) Protocol CDC IRB # 4167 BB IND 11184 , Version Number 7.0 September 21, 2016.