injectable Hydrocortisone (100mg) intramuscularly. One mL of Adrenaline (1:1000) may be injected intramuscularly at the same time as the Antitoxin. Administration of hydrocortisone or adrenaline may be repeated if necessary. In some cases, symptoms such as itching, urticarial 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 :

Diphtheria Antitoxin should be stored at a temperature between 2°C and 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 intradermally 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 manifestations should be taken as positive test.

e) A negative skin test should not be assumed by the physician that no anaphylactic reaction will occur.

f) In all cases receiving Serum, patient must be observed for an hour after administration.

PRESENTATION

Diphtheria Antitoxin is supplied as 10 mL liquid in Vial presentation.

BA251.01

Manufactured in India by : *Biological E. Limited*
18/1 & 3, Azamabad, Hyderabad - 500 020, Telangana.
Web : www.biologicale.com

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

DIPHTHERIA ANTITOXIN I.P. 1000 IU/mL

COMPOSITION :

Diphtheria Antitoxin is prepared by hyperimmunizing healthy horses with diphtheria toxoid. Plasma obtained from the hyper-immunized horses which is rich in antibodies against diphtheria toxoid /toxin is enzyme refined, purified and concentrated. The antitoxin has the specific capacity of neutralizing the toxin secreted by *Corynebacterium diphtheriae*, the causative organism of Diphtheria.

INDICATIONS:

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 (Purified Toxoid Aluminium Phosphate) or adsorbed diphtheria tetanus vaccine, (DT Vaccine adsorbed PTAP, which protects against both diphtheria and tetanus) and followed after 1 to 2 months with a 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 for serum sensitivity (see below for reactions to horse serum). In addition, antihistamines and corticosteroids may be administered. It is advised that after recovery from diphtheria, the patients should be actively immunized for long term protection by use of two doses at an interval of 1 to 2 months with adsorbed diphtheria vaccine or with adsorbed diphtheria tetanus vaccine.

REACTION TO HORSE SERUM :

Injection of Diphtheria Antitoxin in horse-serum-sensitive individual 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 intradermally 0.1 mL of diphtheria antitoxin diluted 1:10 and the patient is observed for 30 min 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 urticarial or fall of blood pressure, these should be treated with 1mL of 1:1000 adrenaline repeated 15 min. later if necessary. In allergic individuals, the diphtheria antitoxin is to be injected 15 to 30 mins, after administration of antihistamines such as injectable Antihistamine (100 mg) and