Diphtheria

A single diphtheria anti-toxin (equine), made by the Institute of Immunology, Croatia is currently being supplied in the UK

Dispensed in vials of: 10,000 IU in 1ml

Indications:
1. For suspected diphtheria cases

2. For treatment of confirmed cases

(refer to '*Public health control and management of diphtheria (in England and Wales) 2015 Guidelines*' available at
https://www.gov.uk/government/publications/diphtheria-public-health-control-and-management-in-england-and-wales

Notes:
Diphtheria anti-toxin is no longer used in the UK for diphtheria prophylaxis.
Unimmunised contacts should be given diphtheria-containing vaccine and antibiotic prophylaxis.

Dosage:

Dosage for intramuscular diphtheria anti-toxin from the Institute of Immunology is determined by the severity and duration of the disease as follows:

Type of diphtheria	**Dosage adults and children**
Laryngeal or pharyngeal disease of 48 hrs duration	20,000 to 40,000 IU
Nasopharyngeal disease	40,000 to 60,000 IU
Systemic disease of 3 or more days' duration, or any patient with diffuse swelling of the neck ('bull neck')	80,000 to 100,000 IU
Skin lesions only (for cases where treatment is indicated)	2,000 to 40,000 IU

Please note this guidance may differ from the dosage instructions in the SmPC distributed with the product. In this instance the guidance above should be followed.

Please read 'Administration' section thoroughly prior to giving anti-toxin

Timing:

Any delay in administration of anti-toxin may result in an increased dose requirement and decreased effectiveness. If diphtheria anti-toxin is not given until three days after symptoms appear, the dose should be doubled. In very severe cases, half the first dose can be administered diluted with saline solution by slow intravenous infusion.

NB: In most cutaneous infections, large-scale toxin absorption is unlikely and therefore the risk of giving anti-toxin is usually considered substantially greater than any benefit. Nevertheless, if the

ulcer in cutaneous diphtheria infection is sufficiently large (i.e. more than $2cm^2$) and membranous, then anti-toxin would be justified.

Precautions for Use*:*
Prior to administering, a detailed history should be taken including:

- previous administration of equine anti-toxin
- known allergic conditions (asthma, eczema etc.)

Administration:

If a patient has not previously received equine anti-toxin the complete dose can be administered (except in patients with a personal or family history of allergy diseases such as asthma or eczema - see below). Give the entire treatment dose of antitoxin intravenously (or intramuscularly) in a single administration (except for series of injections needed for desensitization). When using the intravenous route, the antitoxin should be diluted in physiologic saline and administered slowly over several hours.

If a patient has previously received equine anti-toxin without allergic reaction, a dose of 0.2ml should be administered subcutaneously. The remainder of the dose can be administered intramuscularly after at least 30 minutes if no allergic reaction occurs.

If a patient has previously had a local or general reaction after receiving equine anti-toxin, or has a known allergic condition such as asthma or eczema, desensitization should be tried with 0.2ml of a 1:10 dilution subcutaneously, and after 30 minutes with 0.2ml undiluted solution. If in the next 30 minutes there is no reaction, the remaining quantity of anti-toxin can be administered intramuscularly.

An anaphylactic reaction, should it occur, will be immediate so ensure adrenaline is readily available.

Diphtheria anti-toxin (equine) must not be administered during pregnancy.

Repeated doses of DAT after an appropriate initial dose are not recommended and may increase the risk of adverse reaction.

Appropriate antimicrobial agents in full therapeutic dosages should be started.

Side Effects:

Administration of diphtheria equine anti-toxin may cause hypersensitivity reactions. Reactions occur in individuals previously sensitized to equine anti-toxin or horse proteins either through previous administration on in some other way. Reactions to the anti-toxin may manifest as an anaphylactic reaction and/or serum sickness.

An anaphylactic reaction is immediate.

Serum sickness occurs in a small number of patients 7-12 days after the first injection or 3-5 days in patients who have previously received equine anti-toxin. Symptoms include more generalised erythema, urticaria, itching, and occasionally fever, pain and oedema of the joints and lymph nodes.

The incidence of anaphylactic reaction and serum sickness depends on the quantity of the anti-toxin administered during treatment.

Storage

Store at 2º to 8º C. Once the vial is opened, the preparation must be used immediately.