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This information is intended for use by health professionals

1. Name of the medicinal product

Tetanus Antitoxin (Equine) Injection.

2. Qualitative and quantitative composition

Tetanus Antitoxin 1 500 u/mL, Cresol 0,3% as preservative.
Tetanus Antitoxin 10 000 u/mL, Cresol 0,3% as preservative.

3. Pharmaceutical form

Solution for infusion.

Colourless, clear liquid with having a slight odour due to the preservative

4. Clinical particulars

4.1 Therapeutic indications

Used to provide temporary passive immunity in the prevention and treatment of tetanus.

For those started with tetanus symptoms or in suspension. Tetanus Antitoxin should be given immediately together with surgical and other clinical administration at the same time.

For those openly wounded, especially those wounded deeply and contaminated seriously, and in danger of being infected with tetanus, prophylactic injection of tetanus antitoxin should be given at once. Patient who have had precious injection of tetanus toxoid should be boosted with one more injection of tetanus toxoid (but not tetanus antitoxin). To those who haven't had precious tetanus toxoid injection or without a clear history of immunization, both antitoxin and toxoid should be given for prophylaxis and permanent immunocompetence.

4.2 Posology and method of administration

The right site forsubcutaneous injection of the Tetanus Antitoxin is around the deltoid muscle of the upper-arm. If tetanus toxoid is to be given at the same time, separate sites are desirable. The right site for intramuscular injection is the centre area of the deltoid muscle or the lateral upper part of the gluteous maximus.

Intravenous route should not be used until no untoward reaction occurs after intramuscular or subcutancous injection. Intravenous injection should be done slowly enough: no more than 1ml/min at the beginning and don't exceed 4ml/min afterward.

The total volume for a single dose should be no more than 40ml for adults and no more than 0.8ml/kg body weight for children. Tetanus antitoxin may be diluted with dextrose solution or physiological saline for intravenous drip. The drip must be stopped at once if any untoward reaction occurs.

Prophylactic use:

Tetanus Antitoxin (equine) should not be used in the routine treatment of traumatic wounds. If the wound is extensive, with a high risk of tetanus infection, antitoxin, (preferably the human immunoglobulin) may be injected intramuscularly at the earliest possible moment after infliction of the injury. If equine antitoxin is used, the dose is usually from 1500 to 6000 units.

Active immunisation with Adsorbed Tetanus Vaccine should begin simultaneously with the use of this preparation or a booster injection of Tetanus Vaccine should be given if the patient has previously been immunised. The vaccine should be injected at a different site to that used for the antitoxin. Antitoxin should never be used if a booster dose of Tetanus vaccine would suffice.

IT MUST BE KEPT IN MIND THAT THE DANGER OF TETANUS IS NEVER PAST UNTIL THE WOUND HAS THOROUGHLY BEEN CLEANED AND EVERY PARTICLE OF FOREIGN BODY HAS BEEN REMOVED FROM THE INJURED SITE.

Therapeutic use:

The full and adequate dose, possibly of the order of 100,000 units depending on the severity of the symptoms, should be given as soon as tetanus is suspected; at least some of the antitoxin should be given intravenously.

4.3 Contraindications

Don’t use on patients with hypersensitive to tetanus antitoxin.

Not recommended for pregnant women; Even no connection has been found between congenital malformations or spontaneous abortion with administration of tetanus antitoxin during pregnancy.

This preparation of Tetanus Antitoxin (equine) should not be used if Human Antitetanus Immunoglobulin inj. is available.

4.4 Special warnings and precautions for use

Before use, the ampoule package must be examined with care, Any broken ampoules,or ampoules containing in-dissolved precipitates or particles must be discarded.

Before injecting antisera, information should be obtained whenever possible as to whether previous injections of antisera have been received and whether the patient is subject to hypersensitivity disorders. Sensitivity testing should be performed before the administration of antisera. The patient must be kept under observation after the administration of doses of antisera. Adrenaline injection and resuscitation facilities should be available.

A sensitivity test should be done by: Dilute the antitoxin 1:10 with physiological saline (i.e.0.1ml antitoxin +0.9ml saline), and inject 0.05ml of the diluted antitoxin intracutaneously on the flexor surface of the forearm. A positive reaction characterized by erythema, edema or infiltration appearing in 15-30 minutes denotes

hypersensitiveness to horse serum preparation. A negative reactor may be treated in the usual manner,a positive reactor must be desensitixed when antitoxin administration is indispensable.

The following desensitization procedure may be recommended: dilute the antitoxin 1:10 with sterile physiological saline. Inject subsutaneously 0.2ml at first, observe for 30 minutes. If no reaction occurs,give another injection with increased dose. If no reaction occurs, give a third injection, and so fourth , if still no reaction occurs then the administration of undiluted antitoxin can be started.

Adrenaline should always be at hand. In case of anaphylaxis, adrenaline should be given at once. All patients developed hypersensitive reactions following injection should be handled properly.

4.5 Interaction with other medicinal products and other forms of interaction

Tetanus toxoid will neutralise Tetanus immunoglobulins and should not be injected into the same site or in the same syringe as a tetanus vaccine.

4.6 Fertility, pregnancy and lactation

Not recommended for pregnant women; Even no connection has been found between congenital malformations or spontaneous abortion with administration of tetanus antitoxin during pregnancy.

4.7 Effects on ability to drive and use machines

Caution is advised when driving and using machines in view of the possible undesired effects such as dizziness and vertigo.

4.8 Undesirable effects

Type I hypersensitivity reaction: anaphylaxis shock may suddenly occur during or after the injection of equine antitoxin with symptoms of gloomines or dysphoria, pale or flush face. chest depression or asthma, could sweat, nausea or abdominal pain, weak and rapid pulses, hypotension or collapse in severe case. The patient will die soon if without emergent treatment.

Serum sickness (Type III hypersensitivity reaction,) may occur, frequently 7 to 10 days after the injection. The main symptoms are urticaria, high fever, lymphadenopathy, local swollen and occasionally albuminuria, vomiting. Joint pain as well as erythema, itch and edema at the vaccination site.

4.9 Overdose

No data available

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Systemic immune sera and immunoglobulins preparations,

ATC code: J06AA02

Mechanism of action

Neutralises the toxin produced by Clostridium tetani.
The toxin has a high affinity for nerve tissue and antitoxin is unlikely to have an effect on toxin that is no longer circulating.

5.2 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Chloride ; cresol; Water for Injection

6.2 Incompatibilities

No Data available

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Keep the ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

Transparent 1 ml PhEur type 1 glass ampoules.

Pack sizes:

10 ampoules per Box

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Ningbo Voice Biochemic Co., Ltd.

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