Patient information leaflet.
Please read this leaflet carefully as it contains important information on the use of this product. If you have any queries, please consult your doctor or pharmacist.

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Tetanus Antitoxin 1500 IU Prophylactic (Equine)

Description:

Tetanus anti-toxin is a solution prepared from purified plasma of healthy horses which have been immunized by repeated injection with tetanus toxin. The serum is prepared from whole equine immune plasma by pepsin digestion, controlled heating and ammonium sulphate precipitation followed by purification and sterilization

Tetanus antitoxin is intended for intramuscular injection

Composition:

Each (1ml) contains:
Tetanus antitoxin 1500 I.U.
Tricresol as preservative ≤ 0.35%

Clinical Pharmacology:

C. tetani is a gram-positive, spore-forming, strictly anaerobic bacterium. Spores are prevalent in the environment, particularly in the soil of warm and moist areas, and may be carried in the intestinal tracts and feces of humans and animals. Manure-treated soil may also contain a large number of spores. C. tetani enters the human body through contaminated wounds or tissue injuries including those resulting from unclean deliveries, burns, surgery, and dental extractions. The site of entry is in some cases unknown or no longer visible at the onset of symptoms. Tetanus is not transmitted from person to person. Under favorable anaerobic conditions, such as in devitalized or necrotic tissue, or dirty wounds, the dormant spores may convert to active toxin-producing tetanus bacilli. The most important toxin of C. tetani is the highly potent tetanospasmin. This toxin blocks inhibitory neurotransmitters in the central nervous system and causes the muscular rigidity and spasms typical of generalized tetanus. -The incubation period of non-neonatal tetanus usually varies between 3 and 21 days after infection. Three clinical presentations are characteristic of tetanus infection: localized, cephalic, and generalized tetanus.
1-Localized tetanus is uncommon; it is characterized by sustained contraction of the muscles in the same area as the injury site.
2-Cephalic tetanus is a rare form of the disease associated with ear infections (otitis media) or head lesions. It presents clinically as cranial nerve palsies.
3-Generalized tetanus occurs in >80% of cases, presenting as a generalized spastic disease. Characteristic features of disease onset are early spasms of the muscles of the jaw known as trismus or lockjaw (inability to open the mouth). Spasm of the facial muscles produces risus sardonicus, a distinctive facial expression that resembles a forced grin. Subsequently, sustained spasm of the muscles of the back leads to opisthotonos, the backward arching of the head, neck and spine, and to sudden generalized seizure-like spasms, frequently in response to stimuli. Spasm of the glottis may cause sudden death. In neonatal tetanus, generalized spasms are commonly preceded by the inability to suck or breastfeed and excessive crying. The overall severity of generalized tetanus disease and the case-fatality rate are highly variable.
Tetanus antitoxin neutralizes the toxin produced by C. tetani, the toxin has high affinity for nerve cells, antitoxin neutralizes the circulating toxin only but not the toxin attached to the nerve cells.
Primary immunization with tetanus toxoid with subsequent maintenance of timed boosters is recommended to protect all age groups.

Indication:

It is used to provide temporary passive immunity in the prevention of tetanus disease.

Dosage and Administration:

(For Children and Adults)

For prophylaxis: a dose of 1500 - 3000 I.U. of tetanus antitoxin should be injected intramuscularly (after sensitivity test) as soon as possible after tetanus prone injury such as wounds contaminated with soil or dirt. Sensitivity test should be done before administration of antitoxin serum (see precautions).

Adverse Effects:

Anaphylaxis to horse serum may occur in some rare cases in the form of hypotension, dyspnea, urticaria and shock. adrenaline injection 1: 1000, antihistaminic and cortisone should be available and ready for the treatment of anaphylaxis.
Serum sickness: may occur 7-10 days post-injection of the antitoxin serum symptoms including fever, vomiting, diarrhea, joint and muscle pain, lymphadenopathy, bronchospasm, urticaria, nephritis, myocarditis, neuritis, polyarthritis and uveitis have been reported as rare complications of Serum sickness
It is treated with antihistaminics and corticosteroids.

Reporting of adverse reactions:

If you get any adverse reactions, talk to your doctor or pharmacist. This includes any possible adverse reactions not listed in this leaflet. You can also report adverse reactions via the Egyptian reporting system:
Name: Egyptian Pharmaceutical Vigilance Center
Online reporting
https://www.edaegypt.gov.eg/
PV e-mail for reporting:
pv.followup@ edaegypt.gov.eg **QR Code:**

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Presentation:

-Box containing 10 ampoules each ampoule 1 ml.
-Box containing 120 vial each vial 1 ml.

Contraindications:

Should be used with great caution if the patient is subject to allergic disease (asthma, eczema) or was allergic to any previous antiserum injection or any product prepared from horse.

Precautions:

Before giving any horse serum, history of allergy or previous exposure to horse serum should be reviewed.

Sensitivity test:

Should be done before administration of antitoxin serum

An allergy test is performed on the skin on the outer part of the arm by injecting 0.1 ml of serum (diluted 1/10) (0.1 ml of serum + 0.9 ml of 0.9% salt solution) before giving the dose, and redness continues to appear after 15-30 minutes in case of an allergy.

- In case of a positive allergy test, a desensitization procedure is performed: the serum is diluted to a concentration of 1:10 with a 0.9% salt solution, then 0.2 ml is injected under the skin and observed for 30 minutes. In the absence of a reaction, repeat, but with an increase in the amount and in the absence of a reaction,
the third dose is given and the repetition continues up to 4 times. If it is confirmed that there is no reaction, the full dose is given.
- An ampoule of epinephrine must be prepared to be administered urgently, intramuscularly in the anterior thigh muscle when severe allergic symptoms appear while administering the serum (at a dose of 0.5 ml for adults and 0.01 ml per kg for children)

As recommended by the WHO, anti-shock measures including: Epinephrine 1:1000, corticosteroids, airway, oxygen, calcium salts and antihistaminics should be readily available prior to administration of the antiserum.

If any systemic reaction occurs, serum administration should be discontinued immediately and appropriate antishock measures must be initiated.

N.B. Some studies showed that the use of low dose of subcutaneous adrenaline or parallel infusion of hydrocortisone and antihistamine can reduce acute adverse reaction

Constant attendance and monitoring of vital signs and any untoward reaction are mandatory during antiserum administration for at least 2 hours.

The antitoxin should not be used if turbid, expired or showing precipitation

There is no enough data about the safety of the product during pregnancy; therefore, the risk should be outweighed against the benefit

Storage:

Store at 2-8 °C. Avoid freezing.
Used Immediately after opening.

Shelf life:

Written on the label & box.

This is a medicament.
-A medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you.
-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
-The doctor and the pharmacist are experts in medicine, its benefits and risks.
-Do not try yourself to interrupt the period of treatment prescribed.
-Do not repeat the same prescription without consulting your doctor.
-Keep out of reach of children.

Manufactured by:
The Egyptian Company for Production of Vaccines, sera and Drugs (EGYVAC).
One of the affiliates of The Holding Company for Biological Products and Vaccines

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