TETANUS ANTITOXIN

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SHARJVAX®
1500 IU/ 0.7 mL
Solution for Injection (Equine)
IMMUNE SERA

Formulation:
Each 0.7mL contains
Tetanus Antitoxin, USP .....1500 IU
NaCl 0.9%
m-Cresol..... ≤ 0.25%
Water for Injection q.s.
Modified Globulin Form Antitetanus Horse Serum Intramuscular

Product Description:
Tetanus Antitoxin is a colorless to yellowish clear solution, free from foreign matters, prepared from immunized plasma of healthy horses through the process of ammonium sulfate fractionation and ultra-filtration after being digested with pepsin. It provides temporary passive immunity against tetanus.

Indication:
Prophylaxis against tetanus.

Pharmacodynamics
IMMUNE SERA are antibodies that combine with and neutralize specific toxins which are directed against toxicity of bacteria from animals. Tetanus antitoxin neutralizes the toxin produced by Clostridium tetani.

Dosage and Administration:
Prophylactic Use:
1500 IU – 5000 IU: For adults and children, injection should be repeated after six days when contamination still persists.

For those with tetanus symptoms, Tetanus Antitoxin should be given immediately together with surgical and other clinical remedies.
For deep open wounds and those in danger of being infected, prophylactic injection of Tetanus Antitoxin should be given at once. Patients who have been immunized previously with Tetanus Toxoid, it is advisable to give a booster dose of Tetanus Toxoid only. To those who have not had previous Tetanus Toxoid injection or without clear history of immunization, both antitoxins should be given for prophylaxis and permanent immunity.

The right site for subcutaneous injection of the Tetanus Antitoxin is around the deltoid muscle of the upper arm. If the tetanus toxoid is to be given at the same time, separate sites are desirable. The right site for intramuscular injection is the center area of the deltoid muscle or the lateral upper part of the Gluteus Maximus.

Intravenous route should be used until no untoward reaction occurs after intramuscular of subcutaneous injection. Intravenous injection should be done slowly, not more than 1 mL/min and must not exceed 4 mL/min afterwards.

The total volume for a single dose should not be more than 40 mL for adults and not more than 0.8 mL/ Kg body weight for children. Tetanus Antitoxin may be diluted with dextrose solution or physiological saline intravenous drip. The drip must be stopped at once if any untoward reaction occurs.

Adverse Reaction
1.Type I Hypersensitivity Reaction: Anaphylaxis shock may suddenly occur during or after the injection of equine antitoxin with symptoms of gloominess or dysphasia, pale or flush face, chest depression or asthma, cold sweat, nausea, abdominal pain, weak and rapid pulses, and hypertension in severe cases.
2.Serum Sickness (Type III Hypersensitivity reaction) may occur frequently, 7 to 10 days after injection. The main symptoms are urticarial, high fever, lymphadenopathy, local swelling and occasionally albuminoidal, vomiting, joint pain as well as erythema, itchiness and edema at the vaccination site.

Reporting of Suspected Adverse Reactions
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at first sign/s of adverse reactions.

Contraindication:
- Do not use for patients sensitive of Tetanus Antitoxin
- Not Recommended for Pregnant Women

Precaution and Warning:
Before using the ampoule package must be examined with care. Any broken ampoules containing precipitates or particles must be discarded.

Before injection, the antiserum information should be obtained whenever possible, as to whether previous injection of antiserum has been received or whether the patient in subject has 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.

Sensitivity test should be done. Dilute the Antitoxin 1:10 with physiological saline (i.e. 0.1ml antitoxin +0.9 mL Saline) and inject 0.05 mL of the diluted antitoxin intracutaneously in the flexor surface of the forearm. A positive reaction characterized by erythema, edema or infiltration appearing in 15-30 minutes denotes sensitivity to horse serum preparation. A negative reaction may be treated in the usual manner; a positive reaction must be desensitized when antitoxin administration is available.

The following desensitization procedure may be recommended: Dilute the antitoxin 1:10 with sterile physiological saline. Inject subcutaneously 0.2 mL at first, observer for 30 minutes. If no reaction occurs, give another injection with higher dose, if no reaction occurs give third injection and so forth. If there is still no reaction, then the administration of the undiluted antitoxin can be started.

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

Overdose and Treatment
Consequences of an overdose are not known.

Pregnancy and Lactation
The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials.

It is not known whether tetanus antitoxin is distributed into breast milk. However, problems in humans have not been documented.

Interactions
No known interaction has been established.

Caution:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Storage:
Store at temperatures between 2-8°C. Do not freeze.

Availability:
2 mL Type I Clear Ampoule (Box of 10's)

Manufactured by:
Jiangxi Institute of Biological Products
No. 198 Huoju Avenue, Jinggangshan Economic and Technological Development Zone,
Ji'an City, Jiangxi Province, People's Republic of China

Imported and Distributed by:
SAHAR INTERNATIONAL TRADING INC.
#354 Aguirre Ave., Phase III, BF Homes,
Parañaque City.

FDA Registration No.: BRP-073
Date of Renewal of Authorization:19 February 2021
Date of Revision: 16 July 2022