SUMMARY OF PRODUCT CHARACTERISTICS

1.6 Product information

1.6.1 Summary of Product Characteristics

Summary of Tetanus antitoxin injection 1500I.U.

1. Name of the product

Inoartis (Generic name : Tetanus antitoxin injection 1500I.U.)

2. Qualitative and quantitative composition

$F(ab)^2$	≥ 60%
Protein	≤100 g/L
Sodium Chloride	7.5~9.5 g/L
M-cresol	0.25%
Ammonium Sulfate	≤1.0 g/L
Water for injection	q.s.

3. Pharmaceutical form

Solution for intravenous injection and intramuscularly injection

Clear solution, free of visible particles

Osmolarity: 278 mOsm/l.(approx.)

pH : 3.5 – 6.5

4. Clinical particulars

4.1 Therapeutic indications:

It is indicated for prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain. It is also indicated, although evidence of effectiveness is limited, in the regimen of treatment of active cases of tetanus. A thorough attempt must be made to determine whether a patient has completed primary vaccination.

Patients with unknown or uncertain previous vaccination histories should be considered to have had no previous tetanus toxoid doses. Persons who had military service since 1941 can be considered to have received at least one dose, and although most of them may have completed a primary series of tetanus toxoid, this cannot be assumed for each individual.

Patients who have not completed a primary series may require tetanus toxoid and passive immunization at the time of wound cleaning and debridement.2

4.2 Dosage and administration:

Posology

Adults, the Elderly and Children:

Prophylactic Use:

1500 –3000I.U both for adults and children injection should be repeated after to six days when contaminations still persist.

In those cases who have been immunized previously with tetanus toxoid, it is advisable to give a booster dose of tetanus toxoid only.

For prophylactic use the antitoxin may be given by subcutaneous or intramuscular route.

Therapeutic use:

Tetanus Antitoxin should be administed as early as possible. A case usually requires about 100,000-200,000 on average.

a. Usually, 50,000I.U. of Antitoxin should be given on the first and the following day of illness, and 10,000I.U. is repeated on the third, fourth and the eighth day respectively.

b. The neonates with tetanus should receive 20,000-100,000I.U. Antitoxin within 24 hours of illness either or separate dose.

4.3 Contraindications:

Immunization with Tetanus Toxoid Adsorbed should be deferred in the presence of any acute illness, including febrile illness.

4.4 Warnings and precautions:

General

It should not be given intravenously. Intravenous injection of immunoglobulin intended for intramuscular use can, on occasion, cause a precipitous fall in blood pressure, and a picture not unlike anaphylaxis. Injections should only be made intramuscularly and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel. Intramuscular injections are preferably administered in the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. The gluteal region should not be used routinely as an injection site because of the risk of injury to the sciatic nerve. If the gluteal region is used, the central region MUST be avoided; only the upper, outer quadrant should be used.

Chemoprophylaxis against tetanus is neither practical nor useful in managing wounds. Wound cleaning, debridement when indicated, and proper immunization are important. The need for tetanus toxoid (active immunization), with or without TIG (passive immunization), depends on both the condition of the wound and the patient's vaccination history. Rarely has tetanus occurred among persons with documentation of having received a primary series of toxoid injections.2 See table under

INDICATIONS.

Skin tests should not be done. The intradermal injection of concentrated IgG solutions often causes a localized area of inflammation which can be misinterpreted as a positive allergic reaction. In actuality, this does not represent an allergy; rather, it is localized tissue irritation.

Misinterpretation of the results of such tests can lead the physician to withhold needed human antitoxin from a patient who is not actually allergic to this material. True allergic responses to human IgG given in the prescribed intramuscular manner are rare. Although systemic reactions to human immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactic reactions. Pregnancy Category C

Animal reproduction studies have not been conducted with it. It is also not known whether it can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. it should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

4.5 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 Side effects

1. Type I hypersensitivity reaction: anaphylaxis shock may suddenly occur during or after the injection of equine antitoxin with symptoms of gloomines or dysphoria, plae 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.

2. 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, vomitting. Joiont pain as well as erythema. Itches and edema at the vaccination site.

4.7 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.

5. Pharmacological properties

Pharmacokinetics and pharmacodynamics of the product

Tetanus Antitoxin is prepared from immunized plasma of healthy horses through the process of ammonium sulphate fractionation and ultrafiltration after being digested with pepsin. It provide temporary passive immunity against tetanus, to be used against tetanus prophylatically and therapeutically.

The term antiera includes antitoxins, which are antobodies that combine with and neutralize specific toxins, and antivenins, which are antitoxins directed against the toxic principle of the venoms of poisonous animals. For those started with tetanus symptoms or in suspection. 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. Patients 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. The right site forsubcutaneous injection of the Tetanus Antitoxin is around the deltoid muscle of the upperarm. 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

maximal gluteus. Intravenous route should not be used until no untoward reaction occurs after intramuscular or subcutaneous 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 dilute with dextrose solution or physiological saline for intravenous drip. The drip must be stopped at once if any untoward reaction occurs.

6. Overdose and Treatment

Consequences of an overdose are not known.

7. Pharmaceutical particulars

7.1 List of excipients

Water for injections
Sodium Chloride
M-cresol

7.2 Shelf life

Three years.

7.3 Special precautions for storage

Store at 2-8°C. Protect from light and moisture. Do Not Freeze.

6.5 Nature and contents of container

0.75ml liquid injection in 2ml transparent low borosilicate glass ampoule.

6.4 Package sizes

10ampoules/box

8. Marketing authorization holder

Name: Ningbo Inopha Biotec Co., Ltd.
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8. Manufacturer

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