건 명	Sero-Tet 250IU 인서트 말레이시아(치메로살 제외)		
규 격 (가로x세로)	100x250mm	Q A	오창
		표시문안	6pt
색 상	먹 1도	후 가 공	
업체제작일	2024.02.06.	작 업 처	(주)트리스톤

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칼선 PANTONE 185C

※인쇄진행시, 인쇄사양과 다를경우
녹십자로 즉시 연락주시기 바랍니다.

Tetanus Immune Globulin, Human

Sero-Tet inj.

Description

Sero-Tet is a colorless or yellowish brown and clear or slightly turbid sterile solution containing tetanus immune globulin which is prepared by Cohn fractionation from plasma of individuals with high titers of antibody to the tetanus antigen.
Sero-Tet is prepared from units of human plasma which have been tested and found non-reactive for HBsAg, HIV Ag/Ab and Anti-HCV.

Composition

1mL vial (250 I.U.) contains
Tetanus immune globulin, human ..... 250 I.U.
Aminoacetic acid (as stabilizer) ..... 2.25 w/v%
Sodium chloride (as isotonic agent) ..... q.s.
Glacial acetic acid (pH adjustant) ..... q.s.
Dried sodium carbonate ..... q.s.
Distilled water for injection (diluent) ..... q.s.

Action and Mode or Mechanisms of Action

Tetanus immune globulin (Sero-Tet) is used to provide passive immunization against tetanus in individuals who have no tetanus antibodies of their own. It would neutralize any toxin before it could attach itself to the nervous system.

Pharmacology (summary of pharmacodynamics and pharmacokinetics)

Although the actual serum titer of tetanus antibody indicating immunity has not been established, tetanus antibody titers of 0.01 units or greater are considered indicative of adequate response to tetanus immunization. IM administration of 250 units of tetanus immune globulin generally results in tetanus antibody serum titers of 0.01 units which persist up to 32 days. The half-life of tetanus immune globulin is approximately 28 days.

Toxicology

Test is conducted using 2 different animals, guinea pigs and mice. Results show that the product is free from abnormal toxicity.

Indications

Sero-Tet is used to provide passive immunzation against tetanus infection caused by clostridium tetani

Contraindication

Immunoglobulin A deficiency

Side Effect/Adverse Reactions

There may be local pain. Adverse reactions following administration are infrequent and mild, but severe local and systemic reactions have occurred rarely. Multiple sclerosis in HLA phenotype patients and hypersensitivity reactions had been reported.

Precautions/Warnings

- Should not be administered intravenously
- A separate sterile syringe must be used for each patient to prevent possible transmission of Hepatitis B and other infectious agents.
- Agammaglobulinemia or extreme hypogammaglobulinemia, bleeding disorders.
- In the presence of agammaglobulinemia or hypogammaglobulinemia, an anaphylactoid reaction can occur, especially when the preparation is given by IV injection.

In rare cases, there may exist a hypersensitivity against IgA or other plasma protein determinants.
Should be administered with caution to individuals who have exhibited previous systemic reactions to immune globulin. Epinephrine(0.1-0.5ml, 1:1000) should be available for immediate treatment.

Medical supervision is required for subjects with a known intolerance to blood or blood derivatives.

Use in pregnancy and Lactation

Prenancy is not a contraindication to tetanus prophylaxis. It is not known whether Sero-Tet is excreted in human milk. Because many drugs are excreted in human milk, cautions should be exercised when the product is administered to a lactating or nursing mother.
The safety of the use of Sero-Tet during pregnancy has not been established in controlled clinical trials. According to use of Sero-Tet, the possibility of infection by human parvovirus B19 cannot be totally excluded. Infection by this virus can cause fetal lesions (abortion, fetal hydrops and fetal death). Sero-Tet should be used during pregnancy only when the potential benefits justify the possible risk to the fetus.

Drug Interactions

If tetanus vaccination is required. the injection should be given in another part of the body. After injection of immunoglobulins, wait at least 6 weeks (preferably 3 months) before administering live attenuated virus vaccines (measles, rubella, mumps)

Dosage and Administration

Sero-Tet should only be administerd by intramuscular injection. The usual dosage in adult and children for prophylaxis is 250 IU (1ml).
For severe injuries, such as crushing injuries, severely contaminated wounds or wounds that are more than 24 hours, a dose of up to 500 IU may be require to achieve adequate protection.
In treatment of tetanus, Sero-Tet should be administered not less than 5,000 IU (20ml).
Since passive immunization with tetanus immune globulin against tetanus does not induce lasting immunity, active immunization with Tetanus Vaccine should be given simultaneously.

Symptoms and Treatment for Overdosage and Antidote(s)

It has not been reported even at high doses.

Packing / Pack Sizes

Injection - 250 I.U/1ml vial x single package.

Storage Conditions, User instructions and pharmaceutical Precautions

Store at 2-8°C. Do not freeze.
Shelf Life : 38 months from the date of manufacture.

Name and Address of Manufacturer:

Name : GC Biopharma Corp.
Address of Marketing Office : 107, Ihyeon-ro 30beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do, Korea
Address of Manufacturing Plant : 586, Gwahaksaneop 2-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Korea
Tel: (82) 31-260-9300
Fax: (82) 31-260-9491

Name and Address of Product Registration Holder in Malaysia.

PROPHARM (M) SDN BHD
8, Jln. Udang Harimau 2
Medan Niaga Kepong
51200 Kuala Lumpur
Tel : 03-62436389

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GC Biopharma
GC Biopharma Corp.
586, Gwahaksaneop 2-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Korea