Human Tetanus Immunoglobulin

Sero-Tet

Sero-Tet Prescribing Information

DESCRIPTION
Sero-Tet is a 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.

INDICATION
Sero-Tet is indicated for the prophylaxis of tetanus and the reduction of tetanus symptoms

COMPOSITION
Human Tetanus Immunoglobulin ····· 250 I.U.
Glycine (stabilizer) ····· 2.25 w/v%
Sodium chloride (isotonic agent) ····· q.s.
Glacial acetic acid (pH adjuster) ····· q.s.
Dried sodium carbonate (pH adjuster) ····· q.s.
Water for injection (diluent) ····· q.s.

DOSAGE AND ADMINISTRATION
Sero-Tet should only be administered by intramuscular injection. For the prevention of tetanus at the initial latent period: 250 I.U. by intramuscular injection. For the reduction of tetanus symptoms: should be administered intramuscularly not less than 5,000 I.U.

PRECAUTIONS
- 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.
- Adverse reactions following administration are infrequent and mild, but severe local and systemic reactions have occurred rarely.
- Should be administered with caution to individuals who have exhibited previous systemic allergic reactions to immune globulin. If needed, 0.1-0.5 mL epinephrine (1 : 1,000) or corti sone should be properly administered.

STORAGE
Store below 10 °C without freezing
Shelf life: 38 months

HOW SUPPLIED
250 I.U./vial

Sero-Tet

References
1. Tetanus (US CDC, The Pink book, 13th ed., 2015).
2. Tetanus (www.who.int/immunization/diseases/tetanus/en/).
3. Tetanus (www.CDC.gov/tetanus/).
4. J Infect Chemother. 2011;17(Suppl 1):125-132.
5. Jpn J Acute Med. 1978;2(2):225.
6. N Engl J Med. 1963;268(16):857-862.
7. Morb Mortal Wkly Rep. 2006;55(RR-17).
8. Dtsch Med Wochenschr. 1972;97(10):364-8

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Tetanus - The Disease

1. What is it? [1,2]

Tetanus is an acute, often fatal, disease caused by an exotoxin produced by the bacterium *Clostridium tetani*. It is characterized by generalized rigidity and convulsive spasms of skeletal muscles. Clinical symptoms are muscle spasms, initially of the muscles of mastication causing trismus or “lockjaw”. Trismus can be followed by sustained spasm of the back muscles (opisthotonus) and by spasms of other muscles. Generalized tetanic seizures will ultimately lead to death unless intense supportive treatment is rapidly initiated.

2. How is it transmitted? [1,3]

C. tetani is a spore-forming, anaerobic, gram-positive bacterium. Spores of tetanus bacteria are everywhere in the environment, including soil, dust, and manure. The spores develop into bacteria when they enter the body.

Transmission is primarily by contaminated wounds (apparent and inapparent). The wound may be major or minor. Tetanus may follow elective surgery, burns, deep puncture wounds, crush wounds, otitis media (ear infections), dental infection, animal bites, abortion, and pregnancy.

1 Sero-Tet

1. What is it?

Sero-Tet is a sterile solution of tetanus hyperimmune immunoglobulin which is prepared from large pools of plasma of individuals immunized with tetanus toxoid.

2. What is it used for?

Sero-Tet is indicated for:
a. Post-exposure prophylaxis: immediate prophylaxis after tetanus-prone injuries in patients.
b. Post-diagnosis treatment: treatment of tetanus symptoms in patients diagnosed with tetanus.

2 Prophylaxis of Tetanus

1. Active Immunization [1,2,4,5]

Tetanus can be prevented through immunization with tetanus-toxoid-containing vaccines (TTCV). There are two types of toxoid available—adsorbed toxoid and fluid toxoid. The adsorbed toxoid is preferred because the antitoxin response reaches higher titers and is longer lasting than that following the fluid toxoid. To be protected throughout life, it is recommended that an individual receives 6 doses of TTCV through routine immunization.

Individuals can achieve basic immunity to tetanus after at least 3 doses of tetanus toxoid (a primary series) and antitoxin levels persist at protective levels for at least 5 years after 3-4 doses of tetanus toxoid. Those who have completed a primary series and in whom more than 5–10 years have elapsed since the last dose should receive a booster dose if at risk of developing tetanus.

2. Passive Immunization [4,6]

Tetanus immune globulin (TIG) is used to provide passive immunization against tetanus in individuals who have low or no immunity to tetanus toxin. TIG neutralizes unbound tetanus toxin before it binds to nerve endings.

For critical prevention immediately after injury, 250 IU of TIG for prophylaxis should be given intramuscularly as soon after the injury as possible. Repeated administration is necessary for extensive second degree burns.

Evidence shows that 250 IU of TIG produced antitoxin levels of 0.01 IU/ml or higher in all subjects for 28 days, with the maximum titers obtained on the third to fourth day decreasing over the month. Therefore, an additional 250 IU of TIG was recommended after the 28 day if further surgical wound revision was required or another tetanus-prone injury incurred.

3. Active and Passive Immunization [4,5,7]

If immunity to tetanus is deficient or unknown, or if many years have passed since the immunity was acquired, it is necessary to immediately obtain an effective level of antitoxin in the blood by administering TIG and a tetanus toxoid at the same time. When both TIG and a tetanus toxoid-containing vaccine are indicated, each product should be administered using a separate syringe at different anatomic sites, since neutralization of the toxoid may occur. Adults who have never been vaccinated against tetanus should receive a series of three vaccinations containing tetanus toxoids. The preferred schedule is a single dose of Tdap, followed by a dose of Td >4 weeks after Tdap and another dose of Td 6–12 months later.(Tdap: Tetanus, diphtheria and acellular pertussis vaccine; Td: Tetanus and diphtheria Vaccine)

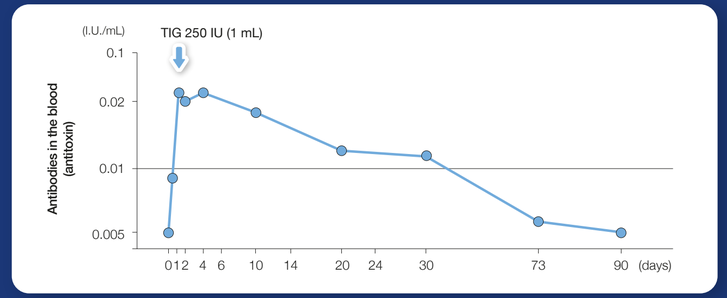

Fig. 1. The course of the tetanus antitoxin titer in serum after IM injection of TIG.
The concentration of antitoxin exceeded the minimum protective level (0.01 IU/mL) within 24 hours after IM injection of TIG 250 IU and was maintained at 0.01 IU/mL or more for 30 days.[8]

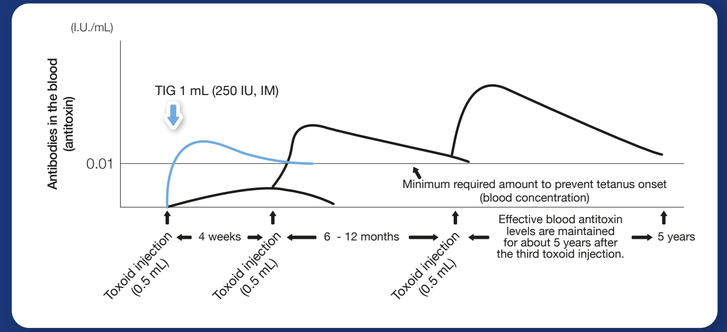

Fig. 2. Principles of active-passive simultaneous immunotherapy for non-immunized tetanus.
When both TIG and a tetanus toxoid-containing vaccine are indicated, each product should be administered using a separate syringe at different anatomic sites.[5]