Tetanus Immune Globulin (Tlg) HyperTET® S/D

Supplier: Grifols Canada Ltd.

INDICATIONS:

- For prophylaxis against tetanus following a major or unclean wound in individuals whose immunization history is incomplete or uncertain (see <u>Tetanus Prophylaxis in Wound</u> <u>Management</u>).
- When a contraindication to a tetanus toxoid-containing vaccine exists and an individual sustains a major or unclean wound.
- In individuals known to have a significant immune deficiency state (e.g., HIV) regardless of their immunization history, following any major or unclean wound.

DOSES AND SCHEDULE:

Adults and children: given as 250 units IM (entire syringe).

TIg should be given as soon as possible, **ideally within 24 hours** after a tetanus prone wound has occurred. However, TIg can be given up to 21 days after sustaining injury (based on the incubation period of 3-21 days).

ADMINISTRATION:

- TIg is supplied in a 250 unit single dose pre-filled disposable syringe.
- The syringe fill volume for each lot is adjusted to ensure a potency of 250 IU/syringe.
- The volume of TIg syringes ranges between 0.75 mL and 1.3 mL.
- The needle on the pre-filled syringe is fixed and cannot be changed.
- See <u>Immune Globulin Preparations (HBIg, Ig, TIg, VarIg, Rablg)</u> for administration information and maximum volume to be administered per site according to age.
- TIg must be given at separate anatomic sites from a tetanus toxoid-containing vaccine.

BOOSTER DOSES:

None.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

None.

PRODUCT COMPONENTS:

Potential allergens: none.

Other components: glycine, sodium carbonate.

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PRECAUTIONS:

- Human Ig products are among the safest blood-derived products available. The method of
 preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV;
 therefore, the risk of transmission is extremely low. However, it is possible that unknown
 infectious agents may be present in such products.
- Give TIg with caution (i.e., in an emergency room setting) if the client has a history of anaphylactic reaction following receipt of any immune globulin product, or a history of anaphylactic reaction to any component of HyperTET® S/D (assess risks versus benefits).
- Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, TIg should only be given to such persons if the expected benefits outweigh the risks, and should be administered in an emergency room setting.
- Special measures should be considered when administering IM injections to people with bleeding disorders. A smaller gauge needle (23 gauge or smaller) should be used and steady, firm pressure should be applied to the injection site for 5 minutes. If there is concern that the injection may stimulate bleeding, the client should connect with their medical specialist.

SPECIAL CONSIDERATIONS:

- Document receipt of TIg in the client's electronic record (e.g., Panorama, PARIS) and/or chart. The following information must be recorded: trade name of product, date, lot number, dosage, route, and site(s).
- Provide a written record to individuals who receive any immune globulin product.
- Regarding TIg and the administration of live vaccines, see <u>Immune Globulin Preparations or</u> <u>Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella</u> <u>Virus</u>.

ADVERSE EVENTS:

Local: soreness. Systemic: fever.

A potential increased risk of thrombosis (blood clots) has been observed within 24 hours of receipt of immune globulin products, especially when given in large doses (i.e., more than 10 mL). Additional risk factors include: age 45 years and older, history of thrombosis, or those with risk factors for thrombosis (e.g., obesity, high blood pressure, diabetes, prolonged periods of immobilization, use of estrogens, a history of heart disease, blood clotting disorders, indwelling central vascular catheters, or diseases that thicken the blood).

^A Daniel WG, Menis M, Sridhar G, et al. Immune globulins and thrombotic events as recorded in a large administrative database in 2008 through 2010. Transfusion. 2012; 52:2113-2121.

^B Menis M, Sridhar G, Selvam N, et al. Hyperimmune globulins and same-day thrombotic adverse events as recorded in a large healthcare database during 2008-2011. Am. J. Hematol. 2013; 88:1035-1040.