

# Tetanus Immune Globulin (Human)

## BIOLOGICAL PAGE

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| <b>Section 7</b>               | Biological Product Information  | <b>Standard # 07.322</b>       |
| <b>Created and approved by</b> | Provincial Immunization Program |                                |
| <b>Approval date</b>           | March 1, 2013                   | <b>Published</b> March 2, 2026 |

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|                                                                                                | HYPERTET®                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                         |                  |                                         |                  |
| Manufacturer                                                                                   | Grifols Therapeutics LLC. (Distributed by Grifols Canada Ltd.)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                         |                  |                                         |                  |
| Classification                                                                                 | Passive: Immunoglobulin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                         |                  |                                         |                  |
| Indications for Provincially Funded Vaccine                                                    | Post exposure prophylaxis:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                         |                  |                                         |                  |
|                                                                                                | <ul style="list-style-type: none"><li>Individuals with tetanus-prone wounds and an unknown/uncertain history of immunization with tetanus-containing vaccine.</li><li>Individuals with tetanus-prone wounds and a history of less than 3 doses of a tetanus-containing vaccine.</li><li>Individuals with humoral immune deficiency (example, individuals with HIV without viral suppression or those with acquired immunodeficiency syndrome, agammaglobulinemia or hypogammaglobulinemia) and a tetanus-prone wound regardless of the time elapsed since the last dose of tetanus-containing vaccine.</li><li>For infants younger than 6 months of age who have not received a 3-dose primary series of tetanus-containing vaccine, decisions on the need for Tetanus Immunoglobulin (TIG) should be based on the mother’s documented tetanus-containing vaccine history at the time of delivery.<ul style="list-style-type: none"><li>Apply the guidelines in the table below based on the birth parent’s immunization history for these situations.</li></ul></li><li>See <a href="#">Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard</a> for identification of a tetanus prone wound</li></ul> |                                         |                  |                                         |                  |
|                                                                                                | History of Tetanus-containing vaccine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Clean Minor Wounds                      |                  | All Other Wounds                        |                  |
|                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Tetanus-containing Vaccine <sup>1</sup> | TIG <sup>2</sup> | Tetanus-containing vaccine <sup>1</sup> | TIG <sup>2</sup> |
|                                                                                                | Unknown or less than 3 doses in vaccine series                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Yes <sup>1</sup>                        | No               | Yes <sup>1,3</sup>                      | Yes <sup>3</sup> |
|                                                                                                | 3 or more doses in a vaccine series and less than 5 years since last booster dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | No                                      | No               | No <sup>1,4</sup>                       | No <sup>4</sup>  |
| 3 or more doses in a vaccine series and 5 years but less than 10 years since last booster dose | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | No                                      | Yes <sup>1</sup> | No <sup>4</sup>                         |                  |
| 3 or more doses in a vaccine series and 10 years or more since last booster dose               | Yes <sup>1</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | No                                      | Yes <sup>1</sup> | No <sup>4</sup>                         |                  |

|                      | HYPERTET <sup>®</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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|                      | <ol style="list-style-type: none"> <li>1. If the age-appropriate tetanus-containing vaccine is not available at the location where the client presents (example, emergency department), the client should be referred to Public Health as soon as practical, ideally within 24 hrs. If it will be more than 72 hours before the client will be seen by Public Health, Tdap vaccine should be given or contact with Public Health made after hours as per zone-specific processes.</li> <li>2. Follow zone-specific processes for accessing TIG.</li> <li>3. Administer at different injection sites using separate needles/syringes.</li> <li>4. Some individuals with humoral immune deficiency (for example, HIV, agammaglobulinemia or hypogammaglobulinemia) may not respond adequately to tetanus containing vaccine. Individuals with humoral immune deficiency who have wounds that are not minor and clean should receive both TIG and age-appropriate tetanus containing vaccine. Administer vaccine regardless of the time elapsed since the last dose of tetanus-containing vaccine.</li> </ol> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• Vaccine alone is not considered adequate for individuals with an inadequate history of tetanus-containing vaccine. <ul style="list-style-type: none"> <li>○ The incubation period for tetanus is 3-21 days, with an average of 10 days.</li> <li>○ Vaccine alone may not boost immunity early enough to give additional protection within the incubation period.</li> </ul> </li> <li>• Give a dose of age-appropriate tetanus-containing vaccine with TIG at the time of injury to ensure the individual is protected against future exposure.</li> </ul> <p><b>Treatment of active cases of tetanus:</b></p> <ul style="list-style-type: none"> <li>• Refer to provincial guidelines and zone processes for follow-up of notifiable diseases <a href="#">Alberta Public Health Disease Management Guidelines: Tetanus</a>.</li> </ul> |
| <b>Schedule</b>      | <ul style="list-style-type: none"> <li>• Administer TIG as soon as possible after a tetanus prone wound has occurred.</li> <li>• Whenever possible, the age-appropriate tetanus-containing vaccine should be given at the same time as TIG, using a separate syringe/needle and at a different anatomical site.</li> <li>• Complete the primary series of tetanus-containing vaccine in individuals never or partially immunized.</li> <li>• If the individual is completely unimmunized, TIG can be considered up to 21 days post injury, with age-appropriate tetanus-containing vaccine administered at the same time.</li> <li>• There is minimal benefit in giving TIG more than one week after injury if: <ul style="list-style-type: none"> <li>○ the individual received a dose of tetanus-containing vaccine for the injury, and</li> <li>○ TIG was delayed, and</li> <li>○ the individual has a history of prior tetanus-containing vaccine.</li> </ul> </li> <li>• Individuals who sustain a subsequent tetanus prone wound, can receive TIG 21 days following a previous dose on a case-by-case basis if: <ul style="list-style-type: none"> <li>○ There is a contraindication to tetanus-containing vaccine, or</li> <li>○ Immunization status is unknown, or</li> <li>○ They have less than 2 doses of tetanus-containing vaccine.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Preferred Use</b> | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Dose</b>          | <p><b>Post-exposure prophylaxis:</b></p> <p><b>For Public Health administration for all ages:</b></p> <ul style="list-style-type: none"> <li>• 250 units (approximately 1 mL).</li> <li>• See product monograph for detailed information on use of preloaded syringe.</li> </ul> <p><b>Treatment:</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

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|                                      | <b>HYPERTET®</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                      | <ul style="list-style-type: none"> <li>An optimal therapeutic dose has not been established. The dosage should be based on the severity of the infection following the attending physician's recommendation.</li> <li>Some experts recommend 500 units, which appears to be as effective as 3,000 to 6,000 units and causes less discomfort.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Route</b>                         | IM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Contraindications/Precautions</b> | <p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>None.</li> </ul> <p><b>Precautions:</b></p> <ul style="list-style-type: none"> <li>Do not administer intravenously.</li> <li>Use with caution in individuals with a history of prior systemic allergic reactions following administration of human immunoglobulin preparations.</li> <li>Individuals with selective immunoglobulin A deficiency have the potential for developing IgA antibodies and could go on to have anaphylactic reactions to subsequent blood products (including Immunoglobulin preparations) that contain IgA. TIG should only be given to previous recipients of TIG if the expected benefits outweigh the risks.</li> <li>HYPERTET is made from human plasma. Products made from human plasma may contain infectious agents that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current viral infections and inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. <ul style="list-style-type: none"> <li>A signed AHS <a href="#">Consent to Treatment Plan or Procedure</a> is required before administering Immunoglobulin products.</li> </ul> </li> <li>Use with caution in individuals with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.</li> </ul> |
| <b>Possible Reactions</b>            | <p><b>Common:</b></p> <ul style="list-style-type: none"> <li>Pain and muscle stiffness at the injection site</li> <li>Slight fever</li> <li>Rash</li> <li>Pruritus</li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>Angioneurotic edema, nephrotic syndrome, and anaphylaxis.</li> <li>Unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Pregnancy</b>                     | <ul style="list-style-type: none"> <li>May be used during pregnancy. <ul style="list-style-type: none"> <li>Intact IgG crosses the placenta increasingly after 30 weeks gestation.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Lactation</b>                     | <ul style="list-style-type: none"> <li>May be used for people who are lactating. <ul style="list-style-type: none"> <li>It is unknown if tetanus immunoglobulin antibodies are excreted into breast milk.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Composition</b>                   | <p>Each pre-filled syringe contains:</p> <ul style="list-style-type: none"> <li>Not less than 250 tetanus antitoxin units per mL</li> <li>15% to 18% protein solution with pH of 4.1-4.8 in 0.16 to 0.26 M glycine</li> <li>Contains no preservative.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Blood/Blood Products</b>          | Made from human plasma.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Bovine/Porcine Products</b>       | <ul style="list-style-type: none"> <li>Does not contain bovine or porcine products.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

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| <b>Latex</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Does not contain latex.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Interchangeability</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Administration with Other Products</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <ul style="list-style-type: none"> <li>TIG can be given at the same time as an age-appropriate tetanus-containing vaccine if the individual is not adequately immunized. <ul style="list-style-type: none"> <li>Use a separate needle and syringe and different anatomical site for each product.</li> </ul> </li> <li>Inactivated vaccines can be given before, concurrently or after TIG. <ul style="list-style-type: none"> <li>No evidence to indicate that administration of TIG interferes with the response to inactivated vaccines.</li> </ul> </li> <li>The recommended spacing between a standard dose (250 units) of TIG and subsequent immunization with VZ, MMR or MMR-Var vaccines is 3 months. <ul style="list-style-type: none"> <li>Do not give TIG at the same time as live virus vaccines.</li> <li>This does not apply to live oral vaccines such as rotavirus.</li> </ul> </li> <li>When it is necessary for TIG to be administered within 14 days after receiving VZ, MMR or MMR-Var vaccine, re-immunization should occur 3 months after TIG, unless serologic testing indicates antibodies to the vaccine(s) were produced.</li> <li>If the immunoglobulin preparation is given more than 14 days post VZ, MMR or MMR-Var immunization, the dose does not need to be repeated.</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>For further information, see <a href="#">Standard for Recommended Immunization Schedules</a>.</li> </ul> |
| <b>Additional Preparation Instructions</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Refer to product monograph for directions regarding use of pre-filled syringe.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Appearance</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Clear or slightly opalescent or pale yellow to light brown solution.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Storage</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>Store at +2°C to +8°C.</li> <li>Do not freeze.</li> <li>Do not use beyond labeled expiry date.</li> <li>Protect from light by storing in original packaging.</li> <li>Supplied in pre-filled syringe with attached needle guard.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Vaccine Code</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | TIG                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Antigen Code</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | TIG                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Licensed for</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | All ages                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Notes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <ul style="list-style-type: none"> <li>2021 January: Removed “Use of TIG must be authorized by MOH/MOH designate.”</li> <li>2024 April 2: New product monograph and new manufacturing process.</li> <li>2024 July 1: References to dTap changed to Tdap to align with national standards.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Related Resources</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"> <li><a href="#">Tetanus Immunoglobulin Information Sheet</a></li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>References</b> <p>American Academy of Pediatrics. (2021). Red Book: 2021-2024 Report of the Committee on Infectious Diseases (32nd ed.). Itasca, IL.</p> <p>Grabenstein, J. D. (2013). ImmunoFacts: Vaccines and Immunologic Drugs (38th Revision ed.). St. Louis, MO: Wolters Kluwer Health.</p> <p>Grifols Therapeutics LLC. (2021, September). HyperTET: Tetanus Immunoglobulin (Human). Product Monograph. <a href="https://pdf.hres.ca/dpd_pm/00062963.PDF">https://pdf.hres.ca/dpd_pm/00062963.PDF</a>.</p> <p>Immunization Action Coalition. Ask the Experts: Pertussis/Tetanus and wound management. Retrieved November 24, 2023, from, <a href="http://www.immunize.org/askexperts/experts_per.asp">http://www.immunize.org/askexperts/experts_per.asp</a>.</p> <p>National Advisory Committee on Immunization. (2023). Canadian Immunization Guide. Public Health Agency of Canada.</p> <p>Primary and Preventative Health Services. (2021, September). Tetanus. In <i>Disease Management Guidelines</i>. Government of Alberta.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

Primary and Preventative Health Services. (2024, April). Tetanus Immune Globulin (Human). In *Alberta Immunization Policy: Biological products*. Government of Alberta.

Primary and Preventative Health Services (2021, January). Tetanus Post-exposure Prophylaxis in Injury/Wound Management. In *Alberta Immunization Policy: Biological products*. Government of Alberta.