

## Tetanus Immune Globulin (Human) Biological Page

<b>Section 7:</b>	<b>Biological Product Information</b>		<b>Standard #: 07.322</b>
<b>Created by:</b>	Provincial Immunization Program Standards and Quality		
<b>Approved by:</b>	Provincial Immunization Program Standards and Quality		
<b>Approval Date:</b>	March 1, 2013	<b>Revised:</b>	July 1, 2024

HYPERTET®																														
<b>Manufacturer</b>	Grifols Therapeutics LLC. (Distributed by Grifols Canada Ltd.)																													
<b>Biological Classification</b>	Passive: Immune Globulin																													
<b>Indications for Provincially Funded Tetanus Immune Globulin</b>	<p><b>Post exposure prophylaxis:</b></p> <ul style="list-style-type: none"> <li>Individuals with tetanus prone wounds and an unknown/uncertain history of active 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 (e.g., HIV infected individuals 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 tetanus containing vaccine dose.</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 TIG should be based on the mother's documented tetanus containing vaccine history at the time of delivery. Apply the guidelines in the table below based on the mother's immunization history for these situations.</li> <li>See <a href="#">Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard</a> for identification of a tetanus prone wound.</li> </ul> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="background-color: #d9ead3;">History of Tetanus Immunization</th> <th colspan="2" style="background-color: #d9ead3;">Clean Minor Wounds</th> <th colspan="2" style="background-color: #d9ead3;">All Other Wounds</th> </tr> <tr> <th style="background-color: #d9ead3;">Tetanus-containing vaccine<sup>1</sup></th> <th style="background-color: #d9ead3;">TIG<sup>2</sup></th> <th style="background-color: #d9ead3;">Tetanus-containing vaccine<sup>1</sup></th> <th style="background-color: #d9ead3;">TIG<sup>2</sup></th> </tr> </thead> <tbody> <tr> <td style="background-color: #d9ead3;">Unknown or less than 3 doses in vaccine series</td> <td style="text-align: center;">Yes<sup>1</sup></td> <td style="text-align: center;">No</td> <td style="text-align: center;">Yes<sup>1,3</sup></td> <td style="text-align: center;">Yes<sup>3</sup></td> </tr> <tr> <td style="background-color: #d9ead3;">3 or more doses in a vaccine series and less than 5 years since last booster dose</td> <td style="text-align: center;">No</td> <td style="text-align: center;">No</td> <td style="text-align: center;">No<sup>1,4</sup></td> <td style="text-align: center;">No<sup>4</sup></td> </tr> <tr> <td style="background-color: #d9ead3;">3 or more doses in a vaccine series and 5 years but less than 10 years since last booster dose</td> <td style="text-align: center;">No</td> <td style="text-align: center;">No</td> <td style="text-align: center;">Yes<sup>1</sup></td> <td style="text-align: center;">No<sup>4</sup></td> </tr> <tr> <td style="background-color: #d9ead3;">3 or more doses in a vaccine series and 10 years or more since last booster dose</td> <td style="text-align: center;">Yes<sup>1</sup></td> <td style="text-align: center;">No</td> <td style="text-align: center;">Yes<sup>1</sup></td> <td style="text-align: center;">No<sup>4</sup></td> </tr> </tbody> </table> <p><sup>1.</sup> If the age-appropriate tetanus containing vaccine is not available at the location where the client presents (e.g., ED), the client should be referred to</p>	History of Tetanus Immunization	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>
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	<p>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.</p> <ol style="list-style-type: none"> <li>2. Follow zone-specific processes for accessing TIG.</li> <li>3. Administer at different injection sites using separate needles/syringes.</li> <li>4. Yes, if known to have an immune compromising condition, especially a humoral immune deficiency (e.g., HIV infection, agammaglobulinemia or hypogammaglobulinemia). Vaccine should be administered as well, regardless of the time elapsed since the last dose of tetanus containing vaccine.</li> </ol> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• For individuals with an inadequate history of tetanus containing vaccine, vaccine alone is not considered adequate for treating a tetanus prone wound because the vaccine may not boost immunity early enough to give additional protection within the incubation period of tetanus (3 to 21 days; average of 10 days).</li> <li>• In addition to TIG, a dose of age-appropriate tetanus containing vaccine should be given 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 as well as 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>• TIG should be given 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 a different anatomical site. Complete the primary series of tetanus containing vaccine in persons never immunized or partially immunized.</li> <li>• If the individual received a dose of tetanus containing vaccine for an injury but TIG is delayed, and the individual has a history of prior tetanus containing vaccine, there is minimal benefit in administering TIG more than a week after injury.</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>• Individuals with a tetanus prone wound who have a contraindication to tetanus containing vaccine, or whose immunization status is unknown, or have less than two doses of tetanus containing vaccine, can receive TIG 21 days following a previous dose, on a case-by-case basis, should a subsequent tetanus prone wound be sustained.</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> <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> </ul>

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	<ul style="list-style-type: none"> <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 clients 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 immune globulin 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 immune globulin 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>As with any immunization, 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>Should be administered during pregnancy if indicated. Intact IgG crosses the placenta from maternal circulation increasingly after 30 weeks gestation.</li> </ul>
<b>Lactation</b>	<ul style="list-style-type: none"> <li>Breastfeeding does not represent a contraindication to any maternal immunization.</li> <li>It is not known if tetanus immunoglobulin antibodies are excreted into breast milk.</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> </ul> <p>Contains no preservative.</p>
<b>Blood/Blood Products</b>	Made from human plasma.
<b>Bovine/Porcine Products</b>	<ul style="list-style-type: none"> <li>No bovine products.</li> <li>No porcine products.</li> </ul>
<b>Latex</b>	No latex.
<b>Interchangeability</b>	N/A
<b>Administration with</b>	<ul style="list-style-type: none"> <li>Passive immunization with HYPERTET® should be undertaken concomitantly</li> </ul>

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<b>Other Products</b>	<p>with active immunization using an age-appropriate tetanus containing vaccine if individual is not adequately immunized.</p> <ul style="list-style-type: none"> <li>• When administering TIG and tetanus containing vaccine concurrently, use separate needles/syringes and different anatomical sites.</li> <li>• There is no evidence indicating that administration of TIG would interfere with the response to inactivated vaccines. Inactivated vaccines can be given before, concurrently or after TIG.</li> <li>• The recommended interval between a standard dose (250 units) of TIG and subsequent immunization with varicella or MMR vaccines is 3 months. TIG cannot be given concurrently with live virus vaccines. This does not apply to rotavirus or other oral vaccines.</li> <li>• When it is necessary for TIG to be administered within 14 days after receiving MMR or varicella vaccine, the immunization with MMR or varicella should be repeated 3 months after the TIG unless serologic testing indicates that antibodies to the vaccine(s) were produced. If the immune globulin preparation is given more than 14 days post MMR or varicella 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 #03.110 <a href="#">Standard for Recommended Immunization Schedules</a></li> </ul>
<b>Appearance</b>	Transparent to slightly opalescent (essentially colourless). May develop slight granular deposit during storage.
<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 the labeled expiry date.</li> <li>• Store in original packaging, when possible, to protect from light.</li> <li>• Supplied in pre-filled syringe with attached needle guard. Refer to product monograph for directions regarding use of pre-filled syringe.</li> </ul>
<b>Vaccine Code</b>	TIG
<b>Antigen Code</b>	TIG
<b>Licensed for</b>	All ages
<b>Program 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>• Tetanus Immune Globulin Information Sheet</li> </ul>	
<b>References:</b>	
<ol style="list-style-type: none"> <li>1. Alberta Health. (2021, September 24). Alberta Public health disease management guidelines: tetanus. <a href="https://open.alberta.ca/publications/tetanus">https://open.alberta.ca/publications/tetanus</a></li> <li>2. Alberta Health, Health System Accountability and Performance Division. Alberta Immunization Policy. (2024 April 2). Tetanus Immune Globulin (Human).</li> <li>3. Alberta Health (2021, January 1). Alberta Immunization Policy. Tetanus Post-exposure Prophylaxis in Injury/Wound Management.</li> <li>4. American Academy of Pediatrics. (2021). Red Book: 2021-2024 Report of the Committee on Infectious Diseases (32nd ed.). Itasca, IL.</li> <li>5. Grabenstein, J. D. (2013). ImmunoFacts: Vaccines and Immunologic Drugs (38th Revision ed.). St. Louis, MO: Wolters Kluwer Health.</li> <li>6. 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>.</li> </ol>	

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7.	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> .
8.	National Advisory Committee on Immunization. (2023). Canadian Immunization Guide (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. <a href="http://www.canada.ca/en/public-health/services/canadian-immunization-guide.html">www.canada.ca/en/public-health/services/canadian-immunization-guide.html</a> .