

<b>Section 7:</b>	<b>Biological Product Information</b>	<b>Standard #: 07.322</b>
<b>Created by:</b>	Province-wide Immunization Program Standards and Quality	
<b>Approved by:</b>	Province-wide Immunization Program, Standards and Quality	
<b>Approval Date:</b>	March 1, 2013	<b>Revised:</b> January 1, 2021

HYPERTET® S/D																														
<b>Manufacturer</b>	Grifols Therapeutics Inc.																													
<b>Biological Classification</b>	Passive: Immune Globulin																													
<b>Indications for Provincially Funded Vaccine</b>	<p><b>Post exposure prophylaxis:</b></p> <ul style="list-style-type: none"> <li>• For tetanus-prone wound in individuals of all ages with a history of less than 3 doses of tetanus-containing vaccine whose immunization is unknown, uncertain or incomplete (see Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard # 08.400).               <ul style="list-style-type: none"> <li>○ For infants younger than 6 months who have not received a full 3-dose primary series of tetanus toxoid-containing vaccine, decisions on the need for TIG with wound care should be based on the mother's documented tetanus toxoid immunization history at the time of delivery. Apply the guidelines in the table below based on the mother's immunization history for these situations.</li> </ul> </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>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>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>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>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>1. If the age-appropriate vaccine is not available at the location where the client presents (e.g., ED), 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, dTap vaccine should be given or contact with Public Health made after hours as per zone-specific processes.</p> <p>2. Follow zone-specific processes for accessing TIG.</p> <p>3. Administer at different injection sites using separate needles/syringes.</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>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.</p> <p><b>Notes:</b> Tetanus prone wound/injury:</p> <ul style="list-style-type: none"> <li>• Any wound (other than a clean, minor wound) that is significantly contaminated with material likely to contain tetanus spores and/or demonstrates the presence of necrotic tissue; including, but not limited to: <ul style="list-style-type: none"> <li>○ Wounds contaminated with dirt, feces, soil and saliva; animal bites; puncture wounds; avulsions; and wounds resulting from missiles (gunshots), crushing, burns and frostbite.</li> <li>○ Wounds with devitalized tissue.</li> <li>○ Abscesses, cellulitis, chronic ulcers and other wounds in patients with diabetes mellitus or illicit injection drug use.</li> <li>○ Wounds sustained more than six hours before surgical treatment of the wound/burn.</li> <li>○ Clinical evidence of sepsis.</li> </ul> </li> <li>• For individuals with an inadequate history of tetanus immunization, tetanus vaccine 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 (4 to 21 days; usually 7 to 10 days).</li> <li>• 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="https://open.alberta.ca/publications/tetanus">https://open.alberta.ca/publications/tetanus</a>.</li> </ul>
<b>Schedule</b>	<ul style="list-style-type: none"> <li>• TIG should be given as soon as possible, <b>ideally within 24 hours</b> after a tetanus prone wound has occurred.</li> <li>• In rare circumstances where TIG is not available or there is a delay in the client reporting or presenting for follow up, it can be given up to 21 days after sustaining injury, based on the incubation period of 3-21 days. If more than 21 days or if a tetanus-containing vaccine was given prior to TIG, consult with MOH/MOH designate.</li> <li>• Whenever possible, the age-appropriate tetanus immunization should be given at the same time as TIG using a separate syringe/needle and a different anatomical site. Complete primary series of tetanus containing vaccine in persons never immunized or partially immunized. <ul style="list-style-type: none"> <li>○ Concurrent administration of tetanus toxoid and TIG may delay development of active immunity by several days through partial antigen-antibody antagonism. However, this interaction is not considered clinically significant and does not preclude concurrent administration of both drugs if both are needed (Grabenstein, 2013).</li> </ul> </li> <li>• When age appropriate immunization cannot be given at the same time as TIG, or within 3 days of administration of TIG, dTap vaccine may be considered at the time of the wound assessment and in consultation with the MOH/MOH designate.</li> </ul>
<b>Preferred Use</b>	N/A
<b>Dose</b>	<p><b>Post-exposure prophylaxis:</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>

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	<p><b>Treatment:</b></p> <ul style="list-style-type: none"> <li>• An optimal therapeutic dose has not been established. The dosage should to be based on the attending physician's recommendation.</li> <li>• Some experts recommend 500 units to 3,000 to 6,000 units.</li> </ul>
<b>Route</b>	IM
<b>Contraindications/Precautions</b>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• None known</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 immunoglobulin A deficiency have potential for developing IgA antibodies and could develop anaphylactic reactions to subsequent blood products (including immune globulin preparations) that contain IgA.</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 <i>Consent for Treatment/Procedure</i> is required before administering immune globulin products: <a href="http://www.albertahealthservices.ca/frm-09741.pdf">http://www.albertahealthservices.ca/frm-09741.pdf</a>.</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> </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>• Use only if the benefit outweighs the potential risk.</li> <li>• Intact IgG crosses the placenta from maternal circulation increasingly after 30 weeks gestation.</li> </ul>
<b>Lactation</b>	Can be administered to eligible breastfeeding women.
<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 pre-filled syringe</li> <li>• 15% to 18% protein solution with pH of 6.4 to 7.2</li> <li>• 0.21 to 0.32 M glycine</li> <li>• Sodium carbonate to adjust pH</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>• One material used in the early manufacturing process is of bovine origin, but this material is not present in the final product.</li> <li>• Contains no porcine products.</li> </ul>
<b>Latex</b>	Contains latex in the stopper of the plunger rod and the rubber needle shield.
<b>Interchangeability</b>	N/A

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<b>Administration with Other Products</b>	<ul style="list-style-type: none"> <li>Passive immunization with HYPERTET® S/D should be undertaken concomitantly with active immunization using an age-appropriate tetanus-containing vaccine if individual is not adequately immunized.</li> <li>When administering TIG and tetanus vaccine concurrently, use separate needles/syringes and different anatomical sites.</li> <li>There is no evidence indicating that administration of immune globulin would interfere with the response to inactivated vaccines. Inactivated vaccines can be given before, concurrently or after an immune globulin has been used.</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.</li> <li>When it is necessary for an immune globulin preparation 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 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 Standard for Recommended Immunization Schedules.</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>	
<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>Alberta Health. (2018, May 11). Public health management guidelines: <i>tetanus</i>.</li> <li>Alberta Immunization Policy. Biological Products (2020 December <i>Tetanus Immune Globulin (Human)</i>).</li> <li>Alberta Health. (2018, June 7). Alberta Immunization Policy. <i>Tetanus Post-exposure Prophylaxis in Injury/Wound Management</i>.</li> <li>Grabenstein, J. D. (2013). <i>ImmunoFacts: Vaccines and Immunologic Drugs</i> (38th Revision ed.). St. Louis, MO: Wolters Kluwer Health.</li> <li>National Advisory Committee on Immunization. Canadian Immunization Guide (Evergreen Edition). Ottawa, ON: Public Health Agency of Canada. <a href="https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html">https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html</a></li> <li>Grifols Therapeutics Inc. (2012, February 3). Product Monograph. <i>HYPERTET® S/D Tetanus Immune Globulin (Human)</i>.</li> </ol>	