

## Varicella Zoster Immune Globulin (Human) Biological Page

<b>Section 7:</b>	<b>Biological Product Information</b>	<b>Standard #: 07.351</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> August 1, 2020

VariZIG®	
<b>Manufacturer</b>	Emergent BioSolutions Inc.
<b>Biological Classification</b>	Passive: Immune Globulin
<b>Indications for Provincially Funded Vaccine</b>	<p><b>Post-exposure:</b></p> <ul style="list-style-type: none"> <li>• In consultation with the Zone Medical Officer of Health (MOH) and/or Infectious Disease/Infection Control Specialist, VariZIG® should be considered based on the susceptibility to varicella, significant exposure, increased risk of severe varicella and contraindication for post-exposure varicella vaccine.</li> <li>• VariZIG® is of maximal benefit if administered within 96 hours of the most recent significant exposure to varicella disease.</li> <li>• If more than 96 hours but less than 10 days has elapsed since the last exposure VariZIG® may be used for the purpose of modifying the disease.</li> <li>• VariZIG® should be considered for:               <ul style="list-style-type: none"> <li>○ Susceptible pregnant women</li> <li>○ Newborn infants of mothers who develop varicella disease during the 5 days before to 48 hours after delivery</li> <li>○ Susceptible immunocompromised individuals with congenital or acquired immunodeficiency due to disease or treatment, including:                   <ul style="list-style-type: none"> <li>▪ Individuals receiving high-dose systemic corticosteroid therapy for 2 weeks or longer (prednisone equivalent of 2 mg/kg or more per day OR 20 mg or more per day if weight is greater than 10 kg).</li> <li>▪ Susceptible HIV infected individuals who are severely immune suppressed (CD4 cell count less than 200 x 10<sup>6</sup>/L or CD4 percentage less than 15%)</li> <li>▪ Hematopoietic stem cell transplant (HSCT) recipients should be considered susceptible prior to immunization and not on antiviral medication. Those who have received 2 doses of appropriately spaced varicella vaccine generally would not be considered susceptible.</li> </ul> </li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• Susceptible individuals are those who do not have documented history of two valid doses of varicella-containing vaccine or laboratory evidence of immunity or laboratory confirmation of varicella disease.</li> <li>• Individuals receiving replacement infusions of 400 mg/kg or more of intravenous immune globulin (IVIG) are considered protected and do not require VariZIG® if the last dose of IVIG was received within 3 weeks before varicella exposure.</li> </ul>

	VariZIG®
	<ul style="list-style-type: none"> <li>• For management of significant varicella exposure in a neonatal or pediatric intensive care, consultation with the infectious disease/infection control specialist regarding the potential use of VariZIG® is advised. Hospitalized preterm infants exposed during the first few weeks of life may be candidates for VariZIG® as listed below:               <ul style="list-style-type: none"> <li>○ If less than 28 weeks gestation or birth weight 1,000 g or less, regardless of maternal immunity.</li> <li>○ If 28 or more weeks gestation and mother lacks evidence of immunity against varicella.</li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• Subsequent exposure occurring more than 3 weeks after administration of VariZIG® would require additional doses of VariZIG® if the criteria for post-exposure still exist.</li> <li>• VariZIG® is not available through Alberta Health Services (AHS) public health vaccine depots. Following zone specific process, the product is available to hospital blood banks/hospital lab/Transfusion Medicine Departments through Canadian Blood Services who will arrange for the release and delivery of VariZIG®.</li> <li>• For further disease information refer to <i>Public Health Notifiable Disease Management Guidelines – Varicella (Chickenpox)</i>  <a href="https://open.alberta.ca/publications/varicella-chickenpox">https://open.alberta.ca/publications/varicella-chickenpox</a></li> </ul>
<b>Schedule</b>	<ul style="list-style-type: none"> <li>• One dose given within 96 hours after exposure</li> <li>• Additional doses of VariZIG® may be required if subsequent exposures occur more than 3 weeks after first dose.</li> </ul>
<b>Preferred Use</b>	N/A
<b>Dose</b>	<ul style="list-style-type: none"> <li>• 125 IU/10 kg body weight to maximum of 625 IU</li> <li>• Minimum dose 125 IU</li> </ul>
<b>Route</b>	IM
<b>Contraindications/ Precautions</b>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• Known hypersensitivity to any component of VariZIG®</li> <li>• History of anaphylactic reaction to immune globulins</li> <li>• IgA deficiency: Individuals with immunoglobulin A deficiency have the potential for developing IgA antibodies and could develop anaphylactic reactions to subsequent blood products (including immune globulin preparations) that contain IgA.</li> <li>• Known immunity to varicella zoster virus.</li> </ul> <p><b>Precautions:</b></p> <ul style="list-style-type: none"> <li>• Use with caution in clients with a history of prior systemic allergic reactions following administration of human immunoglobulin preparations.</li> <li>• VariZIG® is made from human plasma. Products made from human plasma may contain infectious agents that can cause disease. Measures to prevent transmission of viral diseases from VariZIG® include screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current viral infections and using manufacturing techniques to inactivate and/or remove certain viruses. Despite these measures, such products could still potentially transmit disease.               <ul style="list-style-type: none"> <li>○ A signed <i>Consent for Treatment/Procedure</i> is required before administering immune globulin products:  <a href="https://www.albertahealthservices.ca/frm-09741.pdf">https://www.albertahealthservices.ca/frm-09741.pdf</a></li> </ul> </li> </ul>

	VariZIG®
<b>Possible Reactions</b>	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>• Pain, bruising, and pruritus at the injection site</li> <li>• Headache, rash</li> <li>• Myalgia, rigors, fatigue, nausea and flushing</li> </ul> <p><b>Uncommon:</b></p> <ul style="list-style-type: none"> <li>• Mild fever and malaise</li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>• Anaphylaxis, allergic reaction</li> <li>• Urticaria and angioedema</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>	If indicated, VariZIG® should be given to susceptible pregnant women who have been exposed to varicella.
<b>Lactation</b>	Should be administered to susceptible breastfeeding women if indicated. It is not known if VariZIG® is excreted in breast milk.
<b>Composition</b>	<p>Each vial contains:</p> <ul style="list-style-type: none"> <li>• Approximately 125 IU anti-varicella zoster virus</li> <li>• 10% maltose</li> <li>• 0.03% polysorbate 80</li> <li>• less than 156 mg human immunoglobulin G</li> </ul> <p>Contains no preservative</p>
<b>Blood/Blood Products</b>	Made from pooled human plasma.
<b>Bovine/Porcine Products</b>	No bovine or porcine products are listed in the Product Monograph ingredients list.
<b>Latex</b>	There is no latex in the vaccine or the vaccine packaging.
<b>Interchangeability</b>	There is no other varicella zoster immune globulin (VZIG) product available for use.
<b>Administration with Other Products</b>	<ul style="list-style-type: none"> <li>• Immunization with live virus vaccines (MMR and varicella) should be deferred for at least 5 months after administration of VariZIG®. VariZIG® cannot be given concurrently with live virus vaccines.</li> <li>• When it is necessary to administer VariZIG® within 2 weeks after receiving MMR or varicella vaccine, the vaccine should be repeated 5 months after the VariZIG® administration.</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>	Following reconstitution, the product should be clear or slightly opalescent.
<b>Storage</b>	<ul style="list-style-type: none"> <li>• Store VariZIG® at +2°C to +8°C. The product should be brought to room or body temperature immediately prior to use.</li> <li>• Discard any unused product.</li> <li>• Do not freeze.</li> <li>• Do not use beyond expiration date.</li> <li>• Store in original package when possible to protect from light.</li> </ul>
<b>Vaccine Code</b>	VZIG

	<b>VarizIG®</b>
<b>Antigen Code</b>	VZIG
<b>Licensed for</b>	Persons of all ages.
<b>Note:</b>	
<b>Related Resources:</b>	
<ul style="list-style-type: none"> <li>• Varicella Immune Globulin Information Sheet</li> </ul>	
<b>References:</b>	
<ol style="list-style-type: none"> <li>1. Alberta Health. (2020, March ). <i>Varicella</i>. Alberta Health, Public Health Notifiable Disease Management Guidelines.</li> <li>2. Alberta Health. (2020, March). Alberta Immunization Policy. <i>Varicella Zoster Immune Globulin</i>. Government of Alberta, Alberta Health.</li> <li>3. Emergent BioSolutions Inc. (2017 December 19). Varicella Zoster Immune Globulin (Human) Sterile Solution for Injection. Product Monograph. <i>VarizIG</i>.</li> <li>4. National Advisory Committee on Immunization. (2018). Canadian Immunization Guide (Evergreen Edition). Ottawa, ON: Public Health Agency of Canada.</li> <li>5. National Advisory Committee on Immunization. (2016 July). Updated recommendations for the use of varicella zoster immune globulin (Varig) for the prevention of varicella in at-risk patients: <a href="https://www.canada.ca/en/public-health/services/publications/healthy-living/updated-recommendations-use-varicella-zoster-immune-globulin-varig-prevention-varicella-risk-patients.html">https://www.canada.ca/en/public-health/services/publications/healthy-living/updated-recommendations-use-varicella-zoster-immune-globulin-varig-prevention-varicella-risk-patients.html</a>.</li> <li>6. Expert opinion of Alberta HSCT physicians. (October 2019).</li> <li>7. American Academy of Pediatrics. (2018) <i>Red book: Report of the Committee on Infectious Diseases</i> (31<sup>st</sup> ed.). Elk Grove Village, IL: Author.</li> <li>8. National Advisory Committee on Immunization. (2015 Update). Varicella Proof of Immunity. An Advisory Committee Statement (ACS). <a href="http://www.healthycanadians.gc.ca/publications/healthy-living-vie-saine/varicella-proof-immunity-2015-varicelle-preuve-immunite/alt/varicella-proof-immunity-2015-varicelle-preuve-immunite-eng.pdf">http://www.healthycanadians.gc.ca/publications/healthy-living-vie-saine/varicella-proof-immunity-2015-varicelle-preuve-immunite/alt/varicella-proof-immunity-2015-varicelle-preuve-immunite-eng.pdf</a></li> </ol>	