

# Herpes Zoster Non-Live Recombinant Vaccine

BIOLOGICAL PAGE

<b>Section 7</b>	Biological Product Information	<b>Standard # 07.215</b>
<b>Created and approved by</b>	Provincial Immunization Program Standards and Quality	
<b>Approval date</b>	September 1, 2021	<b>Revised</b> January 31, 2025

	SHINGRIX
<b>Manufacturer</b>	GlaxoSmithKline Inc.
<b>Classification</b>	Non-live recombinant, AS01 <sub>B</sub> adjuvanted.
<b>Indications for Provincially Funded Vaccine</b>	<ul style="list-style-type: none"> <li>• Solid Organ Transplant recipients 18 years of age and older (pre and post solid organ transplant). <ul style="list-style-type: none"> <li>◦ See <a href="#">Immunization of Adult Solid Organ Transplant Candidates and Recipients</a> for additional information.</li> </ul> </li> <li>• Autologous Hematopoietic Stem Cell Transplant (HSCT) recipients 18 years of age and older (post HSCT). <ul style="list-style-type: none"> <li>◦ See <a href="#">Immunization for Adult HSCT Transplant Recipients</a> for additional information.</li> </ul> </li> </ul>
<b>Serology</b>	<ul style="list-style-type: none"> <li>• Immunity screening after immunization is not recommended. <ul style="list-style-type: none"> <li>◦ See <a href="#">Immunization of Adult Solid Organ Transplant Candidates and Recipients</a> for additional information regarding serology recommendations.</li> </ul> </li> </ul>
<b>Schedule</b>	<p><b>Primary Series:</b></p> <ul style="list-style-type: none"> <li>• Dose 1: Day 0</li> <li>• Dose 2: 2 to 6 months later.</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• Do not immunize persons with active herpes zoster (HZ) with HZ vaccine. <ul style="list-style-type: none"> <li>◦ Vaccine may be considered at least 1 year after an episode of HZ disease.</li> </ul> </li> <li>• SHINGRIX is recommended for those who have received live varicella vaccine prior to SOT transplant. <ul style="list-style-type: none"> <li>◦ SHINGRIX vaccine can be administered 8 weeks after live varicella vaccine.</li> </ul> </li> <li>• SHINGRIX is recommended for those who have received Zostavax prior to solid organ transplant. <ul style="list-style-type: none"> <li>◦ An interval of 1 year is recommended between live attenuated Herpes Zoster (Zostavax) and SHINGRIX.</li> </ul> </li> </ul>
<b>Preferred Use</b>	N/A
<b>Dose</b>	0.5 mL
<b>Route</b>	IM
<b>Contraindications/Precautions</b>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>• Known severe hypersensitivity to any component of the vaccine.</li> <li>• Anaphylaxis to a previous dose of the vaccine.</li> </ul> <p><b>Precautions:</b></p> <ul style="list-style-type: none"> <li>• SHINGRIX is not indicated for prevention of primary varicella infection or for the treatment of HZ or postherpetic neuralgia (PHN).</li> </ul>

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	<ul style="list-style-type: none"> <li>There are limited data available on the use of SHINGRIX in immunocompromised adults 50 years of age or older.</li> </ul>
Possible Reactions	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>Pain, redness, itching and swelling at the injection site</li> <li>Fever, chills</li> <li>Fatigue, malaise</li> <li>Headache, myalgia, arthralgia</li> <li>Nausea, vomiting, diarrhea, abdominal pain.</li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>Allergic reactions</li> <li>Anaphylaxis</li> <li>As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.</li> </ul>
Pregnancy	<p>Consult with the MOH.</p> <ul style="list-style-type: none"> <li>There is no data on the use of SHINGRIX in pregnant individuals.</li> <li>Not routinely recommended for pregnant individuals.</li> <li>MOH will make an individual recommendation based on the risk of disease versus benefit of vaccine.</li> </ul>
Lactation	<p>Consult with the MOH.</p> <ul style="list-style-type: none"> <li>There is no data on the use of SHINGRIX in lactating individuals.</li> <li>Not routinely recommended for lactating individuals.</li> <li>MOH will make an individual recommendation based on the risk of disease versus benefit of vaccine.</li> </ul>
Composition	<p>After reconstitution, one dose (0.5mL) contains:</p> <ul style="list-style-type: none"> <li>50 mcg Varicella Zoster Virus (VZV) glycoprotein E (gE)</li> </ul> <p>AS01<sub>B</sub>Adjuvant System (including suspension):</p> <ul style="list-style-type: none"> <li>50 mcg Quillaja saponaria Molina, fraction 21 (QS-21)</li> <li>50 mcg 3-O-desacyl-4'-monophosphoryl lipid A (MPL)</li> <li>1 mg dioleoyl phosphatidylcholine (DOPC)</li> <li>0.25 mg cholesterol</li> <li>Disodium phosphate anhydrous</li> <li>Potassium dihydrogen phosphate</li> <li>Sodium chloride</li> <li>Water for injection.</li> </ul> <p>Additional excipients - powder (gE):</p> <ul style="list-style-type: none"> <li>dipotassium phosphate</li> <li>polysorbate 80</li> <li>sodium dihydrogen phosphate dihydrate</li> <li>sucrose.</li> </ul>
Blood/Blood Products	Does not contain human blood/blood products.
Bovine/Porcine Products	Does not contain bovine or porcine products.
Latex	Does not contain latex.
Interchangeability	N/A

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<b>Administration with Other Products</b>	<ul style="list-style-type: none"> <li>SHINGRIX may be administered concomitantly with, or at any time before or after, other inactivated vaccines or live vaccines protecting against a different disease.</li> <li>The vaccines should be administered at different injection sites.</li> </ul>
<b>Appearance</b>	<ul style="list-style-type: none"> <li>The reconstituted vaccine is an opalescent, colourless to pale brownish liquid.</li> <li>The lyophilized powder is white.</li> </ul>
<b>Storage</b>	<ul style="list-style-type: none"> <li>Store both lyophilized vial and adjuvant solution at +2°C to +8°C.</li> <li>Protect from light.</li> </ul>
<b>Preparation</b>	<ul style="list-style-type: none"> <li>SHINGRIX must be reconstituted prior to administration.</li> <li>Withdraw the entire contents of the vial containing the adjuvant suspension into a sterile syringe.</li> <li>Add the entire contents of the syringe into the vial containing the lyophilized powder.</li> <li>Shake gently until the lyophilized powder is completely dissolved.</li> <li>Draw up entire content of the reconstituted vial.</li> </ul>
<b>Vaccine Code</b>	Var-SI
<b>Antigen Code</b>	VZ
<b>Licensed for</b>	<ul style="list-style-type: none"> <li>Individuals 50 years of age and older.</li> <li>Individuals 18 years of age and older who are or will be at increased risk of Herpes Zoster due to immunodeficiency or immunosuppression caused by known disease or therapy.</li> </ul>
<b>Program Notes</b>	<ul style="list-style-type: none"> <li>2017 October 13: Licensed for use in Canada.</li> <li>2021 September 1: Implemented for solid organ transplant recipients 18 years of age and older.</li> <li>2023 March 1: Updated to include reports of fever and shivering when co-administered with Pneumococcal 23-valent Polysaccharide (PPV23) Vaccine.</li> <li>2024 January 29: Expanded indications for provincially funded vaccine to include autologous HSCT recipients 18 years of age and older.</li> </ul>
<b>Related Resources</b>	Herpes Zoster (Shingles) Vaccine – SHINGRIX (VAR-SI) Information Sheet
<b>References</b> <p>Alberta Health. (2024, January 29). Herpes Zoster Non-Live Recombinant Vaccine (Shingrix). In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta.</p> <p>Alberta HSCT program physicians. Expert opinion. November 2023. In <i>Alberta Immunization Policy: Herpes Zoster Non-Live Recombinant Vaccine (Shingrix)</i>. Government of Alberta.</p> <p>Alberta Infectious Disease and Solid Organ Transplant program physicians. Expert opinion. November 2019. In <i>Alberta Immunization Policy: Herpes Zoster Non-Live Recombinant Vaccine (Shingrix)</i>. Government of Alberta.</p> <p>GlaxoSmithKline (2022, November 15). SHINGRIX: Herpes Zoster vaccine (non-live recombinant, AS01<sub>B</sub> adjuvanted). Health Canada Drug Product Database. <a href="https://pdf.hres.ca/dpd_pm/00068227.PDF">https://pdf.hres.ca/dpd_pm/00068227.PDF</a></p> <p>Immunize .org. (2022, March 9). Ask the Experts: Zoster (Shingles). National Advisory Committee on Immunization. (2018, August 30). <i>Updated Recommendations on the Use of Herpes Zoster Vaccines: An advisory committee statement</i>. Public Health Agency of Canada.</p> <p>Public Health Agency of Canada. (2023, October). Herpes zoster (shingles) vaccine. In <i>Canadian Immunization Guide</i>. Government of Canada.</p>	