

Section 7:	Biological Product Information	Standard #: 07.215
Created by:	Province-wide Immunization Program Standards and Quality	
Approved by:	Province-wide Immunization Program Standards and Quality	
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SHINGRIX®	
Manufacturer	GlaxoSmithKline Inc.
Biological Classification	Non-live recombinant, AS01 _B adjuvanted
Indications for Provincially Funded Vaccine	Solid Organ Transplant recipients 18 years of age and older (pre and post solid organ transplant). *See Immunization of Adult Solid Organ Transplant Candidates and Recipients for additional information.
Serology	See Immunization of Adult Solid Organ Transplant Candidates and Recipients for additional information regarding serology recommendations.
Schedule	<p>Primary Series:</p> <ul style="list-style-type: none"> • Dose 1: Day 0 • Dose 2: Two to six months later <p>Notes:</p> <ul style="list-style-type: none"> • Persons with active HZ should not be immunized with HZ vaccine. Vaccine may be considered at least one year after an episode of HZ disease. • SHINGRIX® is recommended for those who have received live varicella vaccine prior to SOT transplant. SHINGRIX® vaccine can be administered 8 weeks after live varicella vaccine. • SHINGRIX® is recommended for those who have received Zostavax® prior to transplant. An interval of one year is recommended between live attenuated Herpes Zoster (Zostavax®) and SHINGRIX®.
Preferred Use	N/A
Dose	0.5 mL
Route	Intramuscular Injection
Contraindications/Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> • Known severe hypersensitivity to any component of the vaccine. • Anaphylaxis to a previous dose of the vaccine. <p>Precautions:</p> <ul style="list-style-type: none"> • SHINGRIX® is not indicated for prevention of primary varicella infection or for the treatment of herpes zoster (HZ) or postherpetic neuralgia (PHN). • There are limited data available on the use of SHINGRIX® in immunocompromised adults 50 years of age or older. • Fever and shivering were more frequently reported when Pneumococcal Vaccine, 23-valent Polysaccharide (PPV23) vaccine was co-administered with Shingrix.
Possible Reactions	<p>Common:</p> <ul style="list-style-type: none"> • Pain, redness, itching and swelling at the injection site • Fever, chills • Fatigue, malaise • Headache, myalgia • Nausea, vomiting, diarrhea, abdominal pain

	SHINGRIX®
	<p>Rare:</p> <ul style="list-style-type: none"> • Allergic reactions • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.
Pregnancy	There are no data on the use of SHINGRIX® in pregnant women, therefore use with caution.
Lactation	There are no data on the use of SHINGRIX® in breastfeeding women, therefore use with caution.
Composition	<p>After reconstitution, one dose (0.5mL) contains:</p> <ul style="list-style-type: none"> • 50 mcg Varicella Zoster Virus (VZV) glycoprotein E (gE) • 50 mcg <i>Quillaja saponaria</i> Molina fraction 21 (QS-21) • 50 mcg 3-O-desacyl-4'-monophosphoryl lipid A (MPL) <p>Additional excipients - powder (gE):</p> <ul style="list-style-type: none"> • dipotassium phosphate • polysorbate 80 • sodium dihydrogen phosphate dihydrate • sucrose <p>Additional excipients - suspension (AS01_B adjuvant system)</p> <ul style="list-style-type: none"> • cholesterol • dioleoyl phosphatidylcholine • disodium phosphate anhydrous • potassium dihydrogen phosphate • sodium chloride • water for injection
Blood/Blood Products	Contains no human blood/blood products
Bovine/Porcine Products	Contains no bovine or porcine products
Latex	There is no latex in the vaccine or vaccine packaging
Interchangeability	SHINGRIX® is the only non-live licensed vaccine for the prevention of HZ (shingles) in Canada.
Administration with Other Products	<ul style="list-style-type: none"> • SHINGRIX® may be administered concomitantly with, or at any time before or after, other inactivated vaccines or live vaccines protecting against a different disease. • The vaccines should be administered at different injection sites.
Appearance	<ul style="list-style-type: none"> • The reconstituted vaccine is an opalescent, colourless to pale brownish liquid. • The lyophilized powder is white.
Storage	<ul style="list-style-type: none"> • Store both lyophilized vial and adjuvant solution at +2°C to +8°C. • Protect from light.
Preparation	<ul style="list-style-type: none"> • Shingrix® must be reconstituted prior to administration. • Withdraw the entire contents of the vial containing the adjuvant suspension into a sterile syringe. • Add the entire contents of the syringe into the vial containing the lyophilized powder. • Shake gently until the lyophilized powder is completely dissolved.
Vaccine Code	Var-SI
Antigen Code	VZ
Licensed for	<ul style="list-style-type: none"> • Individuals 50 years of age and older.

SHINGRIX®	
	<ul style="list-style-type: none"> 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.
<p>Program Notes:</p> <ul style="list-style-type: none"> 2017 October 13: Licensed for use in Canada. 2021 September 1: Implemented for solid organ transplant recipients 18 years of age and older. 2023 March 1: Updated to include reports of fever and shivering when co-administered with Pneumococcal 23-valent Polysaccharide (PPV23) Vaccine. 	
<p>Related Resources:</p> <ul style="list-style-type: none"> Herpes Zoster (Shingles) Vaccine – Shingrix (VAR-SI) Information Sheet 	
<p>References:</p> <ol style="list-style-type: none"> Alberta Health, Health System Accountability and Performance Division, Alberta Immunization Policy (2023 March 1). Herpes Zoster Non-Live Recombinant Vaccine (Shingrix®). Expert opinion of Alberta Infectious Disease and Solid Organ Transplant physicians November 2019. Ask the Experts: Zoster (Shingles) Vaccines (immunize.org) Feb 28, 2023 GlaxoSmithKline (2022, November 15). SHINGRIX®: Herpes Zoster vaccine (non-live recombinant, AS01_B adjuvanted). <i>Product Monograph</i>. https://ca.gsk.com/media/6259/shingrix-pm-en.pdf National Advisory Committee on Immunization. (2018). Updated Recommendations on the Use of Herpes Zoster Vaccines. https://www.canada.ca/en/services/health/publications/healthy-living/updated-recommendations-use-herpes-zoster-vaccines.html#a6 National Advisory Committee on Immunization. (2018). Canadian Immunization Guide (Evergreen ed.). Ottawa, On: Public Health Agency of Canada. https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-8-herpes-zoster-(shingles)-vaccine.html#a9 	