Varicella Vaccine

BIOLOGICAL PAGE



Section 7	Biological Product Information	Standard # 07	7.350
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	August 1, 2012	Revised	January 31, 2025

	VARILRIX	VARIVAX III
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.
Classification	Live; attenuated.	
Indications for Provincially Funded	110 exposurer	
Vaccine Vaccine	organ transplant (SOT). Refer to Immunization Age for indications and scheduling information on Any dose of varicella vaccine given before months of age or older. • Children 12 months up to and including 6 years of children with a history of chickenpox discense offered varicella vaccine. • Children with a laboratory confirmed (values age after the age of 12 months do not when both MMR vaccine and varicella vaccine and including 6 years of age, measles, meand including 12 years of age and older varicella disease do not require enditively developed laboratory confirmed including 12 years of age and older varicella vaccine. • Children 7 years up to and including 12 years of age and older vaccine and varicella vaccine. • Children born August 1, 2012 or later with eligible to receive varicella vaccine. • Children born prior to August 1, 2012 who occurring at 12 months of age and older vaccine. • Verbal history of disease after 12 months enditively at 12 months of age and older do children with a laboratory confirmed history at 12 months of age and older do children with no documentation of age-age.	pears of age: vaccine era is not a reliable indicator of immunity. Prox disease should be offered varicella vaccine. Pease occurring prior to 12 months of age should ricella PCR/NAT swab results) history of varicella trequire varicella vaccine. Paccine are indicated for children 12 months up to the umps, rubella and varicella combined vaccine of varicella-containing vaccine and at any point point irmed (varicella PCR/NAT swab results) vaccine a second dose of varicella-containing vaccine. Per of age: In a verbal history of chickenpox disease are on have a verbal history of chickenpox disease will not be offered varicella vaccine at this time. Per of age may be assessed as follows: Per from parental recollection). Per of varicella disease (varicella PCR/NAT swab anot require varicella vaccine. Per propriate varicella vaccines and who have propropriate varicella vaccines and who have icella IgG positive) results at 12 months of age

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- Children with a history of physician diagnosed (confirmed by physician office) varicella or herpes zoster (shingles) do not require varicella vaccine.
- When both MMR vaccine and varicella vaccine are indicated for children 7 years up to and including 12 years of age, measles, mumps rubella and varicella combined vaccine should be considered.
- Individuals 13 years of age and older:

Note

- o Individuals with unknown/uncertain or no history of chickenpox disease and negative serology refer to Serology Section.
- Individuals who have a history of chickenpox disease occurring at 1 year of age and older will not be offered varicella vaccine at this time. See exceptions related to pregnant individuals and health care workers below.
 - History of disease after 12 months of age may be assessed as follows:
 - "pox" scars
 - recollection of disease in individual (or from parental recollection)
 - history of laboratory confirmed (varicella PCR/NAT swab results) varicella disease
 - history of physician diagnosed (confirmed by physician office) varicella or herpes zoster (shingles).
- Serology to determine susceptibility is required for individuals 13 years of age and older with unknown/uncertain or no history of chickenpox disease except for students in the school immunization program (grades 1 to 9) and Ukrainian evacuees.
 - Susceptibility of students in the school immunization program will be based on history of disease or documented varicella immunization. Serological testing for this cohort will not be required.

Exceptions: Pregnant Individuals and Health care workers (HCWs):

- Pregnant individuals identified through routine prenatal screening with negative serology should be offered up to a maximum of 2 doses of varicella-containing vaccine as they present post-partum regardless of disease history, unless presenting with 2 valid doses of varicella-containing vaccine.
- HCWs and post-secondary HCW students without evidence of immunity should be offered
 2 doses of varicella vaccine as they present.
 - Those presenting with documentation of 1 dose of varicella vaccine should be offered a second dose of varicella vaccine.
 - Shingrix doses cannot be counted in a varicella vaccine series.
- Evidence of immunity for non-pregnant HCWs and post-secondary HCW students includes any of the following:
 - Documentation of 2 valid doses of varicella-containing vaccine.
 - Laboratory evidence of immunity (varicella IgG positive).
 - Laboratory confirmation of varicella disease (varicella PCR/NAT swab results).
 - Physician diagnosed shingles disease (confirmed by physician office).
 - Self-reported history or physician diagnosed varicella disease in Canada prior to a routine immunization program:
 - In Alberta, prior to January 2001
 - For start dates of other Canadian jurisdictions see the <u>NACI Varicella Proof of</u> Immunity -2015 Update.
- Individuals who received their first dose of varicella-containing vaccine and at any point subsequently developed laboratory confirmed (varicella PCR/NAT swab results) vaccine modified varicella disease do not require a second dose of varicella-containing vaccine.

VARILRIX VARIVAX III Considerations for Immunocompromised individuals (refer to Serology Section for definition of susceptible individual): Varicella vaccine can be used with caution for select groups of immunocompromised persons as listed below. Although the use of VARIVAX III is off license for children with acute lymphocytic leukemia (ALL) and for individuals receiving other immunosuppressive treatment, either VARILRIX or VARIVAX III can be offered. Medical consultation with the individual's physician(s) should be sought before immunizing immunocompromised persons. Children with acute Must be in remission for 12 months or longer AND Total lymphocyte count of 1.2 x 10⁹/L or greater AND lymphocytic leukemia Not be receiving radiation therapy AND (ALL): Maintenance chemotherapy can be withheld for at least 1 week before to 1 week after immunization. Note: 2 doses of vaccine are recommended for all children that meet the above conditions for ALL. Susceptible persons who have been cured of ALL may be **Cured of ALL** immunized with up to 2 doses starting at least 1 week after completing chemotherapy. HIV infected individuals Children 12 months of age and older who are varicella nonimmune and with CDC clinical category N, A or B and immunologic category 1 or 2 (CD4 counts greater than or equal to 15%) may be immunized with 2 doses of univalent vaccine with a 3-6 month interval between doses. Susceptible adolescents and adults (no previous history of varicella illness or previous varicella immunization and a negative varicella antibody test) with CD4 cell count greater or equal to 200x10⁶/L and greater or equal to 15% may be considered for varicella immunization. Note: It is essential to ascertain with the specialist that the individual conforms to the appropriate clinical and immunologic categories before making the decision to immunize with varicella vaccine. Persons with planned solid organ transplant (SOT), at least 4 Planned solid organ weeks prior to the initiation of immunosuppressant treatment transplant (SOT) and/or transplant and only following consultation with the attending transplant physician. In addition, SOT candidates may be provided a third dose of varicella vaccine if VZ IgG is negative after the second dose, and it is requested by the transplant physician. See: o Immunization for Adult SOT Candidates and Recipients o Immunization for Children Expecting SOT Before 18 Months of Age o Immunization for Children Expecting SOT After 18 Months of Age Child and adult recipients of hematopoietic stem cell Hematopoietic stem cell

transplants (HSCT)

transplants (HSCT) if there is no graft versus host disease.

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		Consultation with the attending transplant physician is recommended. See: o Immunization for Adult HSCT Transplant Recipients o Immunization for Child HSCT Transplant Recipients Note: Varicella immunization is not indicated for persons awaiting HSCT.	
	Isolated immune- deficiency diseases	 People with isolated immunodeficiency diseases as listed below and known intact T-cell systems may be immunized using the same age-appropriate schedule for healthy persons. B cell deficiencies: Isolated humoral (immunoglobulin) deficiency diseases Phagocytic and neutrophil deficiency disorders Complement deficiency diseases. See Section 2.5 of the Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression. 	
	Cured of malignancies other than ALL	Susceptible persons cured of malignancies other than ALL may be immunized 3 months or more after completion of immunosuppressive therapy.	
	Low-dose steroid therapy Other immuno-	Susceptible children and adults on low-dose steroid therapy (less than 2 mg prednisone/kg daily or less than 20 mg/day if weight is greater than 10 kg for less than 2 weeks) or who are taking inhaled or topical steroids may be safely immunized using the age-appropriate schedule for healthy persons. Persons receiving immunosuppressive treatment for example	
	suppressive treatment	high-dose steroids or treatment for renal failure or auto- immune diseases causing immunosuppression, may be considered for varicella immunization if the total lymphocyte count is at least 1,200 per mm ³ (1.2 x 10 ⁹ /L) or there is no other evidence of lack of cellular immune competence.	
	Post-exposure Immunizat	tion:	
	and older of varicella or d When given within 5 d If more than 5 days af provide protection for For disease investigat Alberta public health of the control of the con	ation could be considered for susceptible contacts 12 months of age disseminated zoster cases. days of first exposure, it may prevent or modify varicella disease. after first exposure, the vaccine could still be offered as this will or future exposures. ation, contact assessment and reporting requirements, refer to a disease management guidelines: varicella. In is not recommended for infants under 12 months of age, VZIG may ster Immune Globulin (Human) Biological Page.	
Serology	Susceptible individuals include those: Without a history of disease, or Without age-appropriate varicella immunization, or Without serological evidence of immunity such as negative or indeterminate varicella IgG result.		

VARIVAX III VARILRIX For further information on history of disease, refer to the Indications Section. Note: Healthy individuals that have been previously found to be seropositive do not need to be tested again. **Pre-Immunization Serology:** Varicella IgG serology is indicated for all susceptible individuals 13 years of age and older. Exception: children being immunized as part of the school immunization program in grades 1 to 9. o Pre-immunization serology is not required to determine susceptibility for immunization Use history of disease or documented age-appropriate varicella immunization o This applies to students assessed in the school or clinic settings. Swab results for shingles or varicella vesicles that are positive for varicella zoster (varicella PCR/NAT), or historical varicella IgM positive serology may be used to determine disease history/immunity to chickenpox. Serology is not required for individuals who have received 1 dose of varicella vaccine and who are eligible for a second dose. Complete the series. **Post-Immunization Serology:** Not indicated as commercial laboratory tests are not sensitive enough to detect vaccineinduced antibodies. No further varicella vaccine is required if varicella IgG serology is done and is positive after the first dose of varicella vaccine. Previously immunized individuals who are inadvertently tested are likely to be immune to varicella, even if there is no detectable antibody. **Schedule** Children 12 months up to and including 6 years of age: Dose 1: 12 months of age Dose 2: 18 months of age. Note: Most young children in Alberta routinely receive MMR - Var combined vaccine at 12 months and 18 months of age. See Measles, Mumps, Rubella and Varicella Vaccine Biological Page. The recommended spacing between the first and the second dose is 3 months. If varicella vaccine is given as the first dose, MMR-Var combined vaccine can be administered to complete the series if MMR is also required. o The recommended interval between the 2 vaccines is 3 months. The minimum interval between live vaccines is 4 weeks if rapid protection is required. Children who have received a single dose of varicella-containing vaccine and develop laboratory confirmed (varicella PCR/NAT swab result) varicella disease, do not require the second dose of a varicella-containing vaccine. Children 7 years up to and including 12 years of age: Dose 1: day 0 Dose 2: 3 months after dose 1. Note: The minimum interval between live vaccines is 4 weeks if rapid protection is required.

to complete the series if MMR is also required.

If varicella vaccine is given as the first dose, MMR-Var combined vaccine can be administered

The recommended interval between the 2 vaccines is 3 months.

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 Children who have received a single dose of varicella-containing vaccine and develop laboratory confirmed (varicella PCR/NAT swab result) varicella disease, do not require the second dose of a varicella-containing vaccine.

Individuals 13 years of age and older:

- Dose 1: day 0
- Dose 2: 6 weeks after dose 1.

Note:

- The minimum interval between live vaccines is 4 weeks if rapid protection is required.
- Individuals who received 1 dose under the age of 13 years AND whose birthdate is prior to August 1, 2005 are considered COMPLETE at this time.
- After the start of the second dose varicella vaccine program August 1, 2012, children born on August 1, 2005 or later are eligible for 2 doses of varicella vaccine.

Exceptions:

- Individuals identified through routine prenatal screening are eligible for a maximum of 2 doses of varicella-containing vaccine.
- HCWs and post-secondary HCW students are eligible for a maximum of 2 doses of varicellacontaining vaccine as they present.
- Shingrix doses cannot be counted in a varicella vaccine series.

Spacing Considerations:

Recommended Intervals for MMR and Varicella Containing Vaccines			
Previous Vaccine	Recommended Interval to Next Dose		
Administered	MMR-Var	MMR	Varicella ^{1, 2}
MMR-Var	3 months	3 months	3 months
MMR	3 months	4 weeks	3 months
Varicella ^{1,2}	3 months	3 months	6 weeks or 3 months ³

- For all HSCT recipients and SOT candidates there must be a minimum of 3 months separating 2 doses of varicella vaccine. See:
 - o Immunization for Adult HSCT Transplant Recipients
 - Immunization for Child HSCT Transplant Recipients
 - o Immunization for Adult SOT Candidates and Recipients
 - o Immunization for Children Expecting SOT Before 18 Months of Age
 - o Immunization for Children Expecting SOT After 18 Months of Age
- Individuals infected with HIV, who meet the clinical and immunologic categories under Indications above, should receive 2 doses of varicella vaccine with an interval of at least 3 months between doses. MMR vaccine, if needed, may be administered at the same time.
- 3. An interval of 3 months between doses of varicella-containing vaccines is recommended for individuals under 13 years of age and 6 weeks for individuals over 13 years of age unless they have one of the following conditions: HIV, asplenia/hyposplenia and chronic renal disease. Individuals with these conditions require a minimum spacing of 3 months between doses.
- Univalent varicella vaccine can be administered simultaneously with other live vaccines or separated by an interval of at least 4 weeks. See above for recommended intervals between all measles, mumps, rubella and varicella vaccines.
- If live vaccine was administered at less than the routine intervals outlined above, the dose
 can be considered valid, and vaccine would not need to be repeated if there is a minimum
 interval of at least 4 weeks.

Dose

0.5 mL

Note:

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	 Medical consultation is recommended before proceeding with immunization in children on salicylate therapy. Children with ALL in remission should have maintenance chemotherapy withheld 1 week before and 1 week following immunization. Medical consultation is recommended before proceeding with immunization. Individuals taking long-term antiviral therapy should discontinue these drugs (for example acyclovir, valacyclovir or famciclovir), at least 24 hours before administration of varicella vaccine and up to 14 days after immunization. Medical consultation is recommended before proceeding with immunization. If the vaccine recipient develops a varicella-like rash, cover when possible. When not possible, avoid direct contact for the duration of the rash with susceptible high-risk individuals such as non-immune pregnant individuals, immunocompromised individuals, newborn infants born to parent without documented history of disease or negative serology. 		
Possible Reactions	Common:		
	 Pain, redness, swelling, pruritus, hematoma, induration, stiffness, and numbness at injection site Fever, chills Rash, hives/urticaria, varicella-like rash usually 5 to 26 days following immunization Cough, rhinitis, and pharyngitis Irritability, fatigue, headache, malaise, somnolence Diarrhea, nausea, vomiting Arthralgia, myalgia, abdominal pain Lymphadenopathy. Rare: Anaphylaxis Conjunctivitis Febrile seizures Pneumonitis. Unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information. Post-immunization varicella-like rash: Transmission from a post-immunization rash to susceptible individuals is rare 		
	 Individually evaluate health care workers who develop a post-immunization rash If the post-immunization rash is confined to the injection site and can be covered, generally the individual can continue to work If the post-immunization rash is not confined to the injection site, exclude the individual from work in high-risk patient care areas until the lesions are crusted. For example, areas where there are premature infants and patients who are immunocompromised. 		
Pregnancy	Do not use during pregnancy.		
	 Live vaccines are contraindicated in persons who are pregnant. Avoid pregnancy for at least 1 month following immunization. 		
Lactation	May use for people who are breast/chest feeding. Can be administered to eligible individuals who are breast/chest feeding. It is not known whether varicella vaccine virus is secreted in human milk. Breast/chest feeding should not be discontinued if post-immunization rash develops. Cover rash if possible.		
Composition	Each dose of 0.5 mL reconstituted vaccine contains:	Each 0.5 mL dose of reconstituted vaccine contains:	

	VARILRIX	VARIVAX III	
	 Not less than 10^{3,3} PFU (plaque-forming units) of Oka-strain varicella-zoster virus Amino acids Lactose Mannitol Sorbitol Sterile water for injection (diluent) Residues of neomycin sulphate. 	 A minimum of 1,350 PFU (plaque forming units) of Oka/Merck varicella virus hydrolyzed gelatin monosodium L-glutamate potassium chloride potassium phosphate monobasic sodium chloride sodium phosphate dibasic sucrose urea water for injection (diluent). 	
Blood/Blood Products	Does not contain blood/blood products.	Does not contain blood/blood products however the varicella virus is grown in MRC-5 human diploid cell culture.	
Bovine/Porcine Products	Animal materials from bovine (fetal bovine serum, galactose) origin are not used in the formulation of VARILRIX. They are used as raw materials during the routine manufacturing process. Porcine Products: Animal materials from porcine (trypsin) origin is not used in the formulation of VARILRIX. They are used as raw materials during the routine manufacturing process.	Contains trace quantities of fetal bovine serum from MRC-5 culture media. Porcine Products: Contains porcine products.	
Latex	Does not contain latex.		
Interchangeability	Vaccines may be used interchangeably. • Use the manufacturer recommended dose and schedule.		
Administration with Other Products	 May be given at the same time as other live vaccines. If the live vaccines are not given at the same time, space the vaccines by at least 4 weeks. See Schedule Section for recommended intervals between all measles, mumps, rubella and varicella vaccines. Use a separate needle and syringe for each vaccine. May be given at the same time as other inactivated vaccines. Use a separate needle and syringe for each vaccine. The same limb may be used, if necessary, but different sites on the limb. SHINGRIX can be given a minimum of 8 weeks after live varicella vaccine. Do not give immune globulins (IG) and antibody-containing blood products at the same time as live vaccines. Separate from live vaccines by the specified time frames. This depends on the dosage and the biological. Give varicella vaccine at least 14 days prior to administration of an IG preparation, or blood product, or delay until the antibodies in the IG preparation or blood product have degraded. See Section 7: Guidelines for Intervals Between Immune Globulin and other Blood Products and Live Vaccines in the Standard for Recommended Immunization Schedule. Repeat the vaccine dose after the recommended interval if the interval between administration of vaccine and subsequent administration of an IG preparation or blood product is less than 14 days. See Section 7: Guidelines for Intervals Between Immune 		

	VARILRIX	VARIVAX III	
	Globulin and other Blood Products and Live Vaccines in the Standard for Recommended Immunization Schedule. • Give tuberculin skin tests either before or at the same time as varicella vaccine. If not, delay the tuberculin skin test for 4 weeks following varicella vaccine.		
Appearance	 Slightly cream to yellowish or pinkish coloured powder. Once reconstituted, the liquid may vary from clear peach to pink coloured solution. 	Reconstituted vaccine is clear, colourless to pale yellow liquid.	
Storage	 Store at +2°C to +8°C Protect from light Do not freeze Do not use beyond the labeled expiry date Store diluent at room temperature Use reconstituted vaccine as soon as possible as vaccine is unstable and begins to deteriorate as soon as reconstituted. 		
Vaccine Code	VZ		
Antigen Code	VZ		
Licensed for	All individuals 12 months of age and older as per the indications section.	All individuals 12 months of age and older as per the indications section.	
Off-License Use	 Children starting at 6 months of age to less than 12 months of age expecting solid organ transplant. Third dose for solid organ transplant candidates if VZ IgG is negative after the second dose (only at the request of the transplant physician). 	 Children starting at 6 months of age to less than 12 months of age expecting solid organ transplant. Susceptible adults with HIV meeting clinical criteria. Children with acute lymphocytic leukemia (ALL). Individuals receiving other immunosuppressive treatment. Third dose for solid organ transplant candidates if VZ IgG is negative after the second dose (only at the request of the transplant physician). 	
Notes	 2001 March: Varicella vaccine was made available to non-immune special groups (household contacts of immunocompromised individuals, health care workers known to be susceptible, and women identified through routine pre-natal care). 2001 April: A catch-up program was offered in the grade 5 school immunization program. 2001 July 1: Varicella vaccine was introduced into the 12 month routine childhood immunization visit for all individuals born on or after January 1, 2000. 2002 Spring: A catch-up program was offered during the preschool immunization visit. 2003 April: All other susceptible individuals in Alberta became eligible to receive the varicella vaccine. 2012 August 1: All children born on or after August 1, 2005 became eligible to receive 2 doses of varicella vaccine. With 2 doses of MMR vaccine and 2 doses of varicella vaccine recommended in the routine schedule as of August 1, 2012, MMR-Var became the vaccine of choice at the 12 month and 4 to 6 year immunization appointments. 2018 September 1: Children born August 1, 2012 or later with a verbal history of chickenpox disease became eligible to receive varicella vaccine as they present in child health clinic. Additionally, women identified through prenatal screening and HCWs became eligible to receive varicella vaccine regardless of disease history to a maximum of 2 doses. 		

	VARILRIX	VARIVAX III
	 2021 January 1: Varicella second dose offered at 18 months instead of 4 years of age. 2022 April 25: Included Ukrainian evacuees 13 years of age and older under exception for serology requirement to determine susceptibility. 2023 August 28: Removal of Varilrix as product no longer available in Alberta. Included expert advice allowing off-license use of VARIVAX III in children with acute lymphocytic leukemia (ALL) and persons receiving other immunosuppressive treatment. 2023 October 12: Removal of Contraindications to Varilrix as product no longer available in Alberta. 2024 January 29: Third dose provincially funded for SOT candidates if VZ IgG negative at request of transplant physician. 2024 April 8: Varilrix product available in Alberta. 2024 September 6: Updated to clarify the 2-dose eligibility across the different age groups. 	
Related Resources	Varicella Vaccine Information Sheet (104508)	

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