Varicella Vaccine Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.350**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program Standards and Quality		
Approval Date:	August 1, 2012	**Revised:**	January 1, 2021

	Varilrix®	**Varivax® III**
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.
Biological Classification	Live; attenuated	
Indications for Provincially Funded Vaccine	**Pre-exposure:** • **Infants 6 months of age up to and including 11 months of age** who are candidates for a solid organ transplant. Refer to *Standard for Immunization of Transplant Candidates and Recipients* for indications and scheduling information. **Note:** ○ Any dose of varicella vaccine given before 12 months of age should be repeated at 12 months of age or older. • **Children 12 months up to and including 6 years of age.** **Notes:** ○ Verbal history of disease in the varicella vaccine era is not a reliable indicator of immunity. ○ Children with a verbal history of chicken pox disease should be offered varicella vaccine. ○ Children with a history of chickenpox disease occurring prior to 12 months of age should be offered varicella vaccine. ○ Children with a lab-confirmed history of varicella disease after the age of 12 months do not require varicella vaccine. ○ When both MMR vaccine and varicella vaccine are indicated for children 12 months up to and including 6 years of age, measles, mumps, rubella and varicella combined vaccine should be considered. ○ Individuals who received their first dose of varicella-containing vaccine and at any point subsequently developed laboratory-confirmed vaccine modified varicella disease do not require a second dose of varicella-containing vaccine. • **Children 7 years up to and including 12 years of age.** **Notes:** ○ Children born prior to August 1, 2012 who have a history of chickenpox disease occurring at one year of age and older will not be offered varicella vaccine at this time. • history of disease after 12 months of age may be assessed as follows: ▪ "pox" scars, ▪ recollection of disease in individual (or from parental recollection), ▪ if others in the household had disease, and parent/sibling did not get disease, ▪ history of laboratory confirmed varicella disease, ▪ history of physician diagnosed varicella or herpes zoster (shingles). ○ 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.	

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	• **Individuals 13 years of age and older.** **Notes:** ○ Individuals with unknown/uncertain or no history of chickenpox disease and negative serology – refer to Serology Section. ○ Individuals 13 years of age and older who have a history of chickenpox disease occurring at one year of age and older will not be offered varicella vaccine at this time. **See exceptions related to pregnant females 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), ▪ if others in the household had disease, and parent/sibling did not get disease, ▪ history of laboratory confirmed varicella disease, ▪ history of physician diagnosed 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). • 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 Females and Health care workers (HCWs):** ○ Pregnant Females - Women identified through routine prenatal screening should be offered up to a maximum of two doses of varicella containing vaccine as they present post-partum regardless of disease history unless presenting with laboratory confirmation of immunity (varicella IgG positive). ○ HCWs and Post-secondary HCW Students without evidence of immunity should be offered two doses of varicella vaccine as they present. • Those presenting with documentation of one dose of varicella vaccine should be offered a second dose of varicella vaccine. • While Zostavax® vaccine is not indicated for and should not be used for prevention of varicella disease, it can be considered a valid first dose. This is applicable only for a first dose in a 2-dose varicella vaccine series. (Shingrix doses cannot be counted in a varicella vaccine series). ○ Evidence of immunity for non-pregnant HCWs and post-secondary HCW students includes: • Documentation of two valid doses of varicella containing vaccine; or • Laboratory evidence of immunity; or • Physician diagnosed shingles disease; or • 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 NACI Varicella Proof of Immunity - 2015 Update ○ Individuals who received their first dose of varicella-containing vaccine and at any point subsequently developed laboratory confirmed vaccine modified varicella disease do not require a second dose of varicella-containing vaccine.	

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	Considerations for Immuno-compromised 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. **Medical consultation** with the individual's physician(s) should be sought before immunizing immunocompromised persons.	
	Children with acute lymphocytic leukemia (ALL): (can receive Varilrix® only)	• Must be in remission for 12 months or longer AND • Total lymphocyte count of 1.2 x 10^9/L or greater AND • Not be receiving radiation therapy AND • Maintenance chemotherapy can be withheld for at least 1 week before to 1 week after immunization. **Note:** Two doses of vaccine are recommended for all children that meet the above conditions for ALL.
	Cured of ALL (can receive Varilrix® or Varivax®)	• Susceptible persons who have been cured of ALL may be immunized with up to 2 doses starting at least 1 week after completing chemotherapy.
	HIV infected individuals (can receive Varilrix® or Varivax®)	• Children 12 months of age and older who are varicella non-immune and with CDC clinical category N, A or B and immunologic category 1 or 2 (i.e., 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 200x10^6/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.
	Planned solid organ transplant (can receive Varilrix® or Varivax®)	• Persons with planned solid organ transplant, at least 4 weeks prior to the initiation of immunosuppressant treatment and/or transplant and only following consultation with the attending transplant physician. See: ▪ *Standard for Immunization of Transplant Candidates and Recipients*
	Hematopoietic stem cell transplants (HSCT) (can receive Varilrix® or Varivax®)	• Child and adult recipients of hematopoietic stem cell transplants (HSCT) if there is no graft versus host disease. Consultation with the attending transplant physician is recommended. See: ▪ *Standard for Immunization of Transplant Candidates and Recipients* **Note:** Varicella immunization is not indicated for persons awaiting HSCT.
	Isolated immune-deficiency diseases (can receive Varilrix® or Varivax®)	• People with **isolated immunodeficiency diseases** 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.

<table>
<tr><th></th><th colspan="2">Varilrix®</th><th>Varivax® III</th></tr>
<tr><td></td><td colspan="3">
<table>
<tr><td>Cured of malignancies other than ALL
(can receive Varilrix® or Varivax®)</td><td colspan="2">• Susceptible persons cured of malignancies other than ALL may be immunized 3 months or more after completion of immunosuppressive therapy.</td></tr>
<tr><td>Low-dose steroid therapy
(can receive Varilrix® or Varivax®)</td><td colspan="2">• 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.</td></tr>
<tr><td>Other immuno-suppressive treatment
(can receive Varilrix® only)</td><td colspan="2">• Persons receiving immunosuppressive treatment (e.g. 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.</td></tr>
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• Post-exposure Immunization:
○ Post-exposure immunization could be considered for susceptible contacts of varicella or disseminated zoster cases.
• When given within 5 days of first exposure, it may prevent or modify varicella disease.
• If more than 5 days after first exposure, the vaccine could still be offered as this will provide protection for future exposures.
• Requires consultation with MOH/MOH designate prior to administration, if more than 5 days have passed since exposure.
○ For further guidelines related to post-exposure follow-up refer to the Public Health Notifiable Disease Management Guidelines – Varicella.
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<tr><td>Serology</td><td colspan="3">Susceptible individual includes those without a history of disease, without age-appropriate varicella immunization, or without serological evidence of disease. For further information on history of disease, refer to the Indications Section.
Pre-Immunization serology:
• Varicella IgG serology is indicated for all susceptible individuals 13 years of age and older with the exception of children being immunized as part of the school immunization program (grades 1 to 9).
• For students being immunized as part of the school program (grades 1 to 9), pre-immunization serology is not required to determine susceptibility for immunization – use history of disease or documented age-appropriate varicella immunization.
Post-Immunization Serology:
• Not indicated as commercial laboratory tests are not sensitive enough to detect vaccine-induced antibodies.</td></tr>
<tr><td>Schedule</td><td colspan="3">Children 12 months up to and including 6 years of age:
• Dose 1: 12 months of age
• Dose 2: 18 months of age
Notes:
• Most young children in Alberta routinely receive MMR – Varicella combined vaccine at 12 months of age and at either 18 months or 4 years of age. See Measles, Mumps, Rubella and Varicella Vaccine Biological Page.
• After the start of the second dose varicella vaccine program August 1, 2012, children born on August 1, 2005 or later, will continue to be eligible for two doses of varicella vaccine.</td></tr>
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	Varilrix®	Varivax® III
	• The recommended spacing between the first and the second dose is 3 months. • If varicella vaccine is given as the first dose, MMR-varicella combined vaccine (if MMR also required) can be administered for the other dose to complete the series. The recommended interval between the 2 vaccines is at least 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 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. **Individuals 13 years of age and older** (if susceptible – refer to Serology Section): • Dose 1: day 0 • Dose 2: 6 weeks after dose 1 (See information below in Spacing Considerations) **Note:** The minimum interval between live vaccines is 4 weeks if rapid protection is required. **Note:** • Individuals who received one dose under the age of 13 years AND whose birthdate is prior to August 1, 2005 are considered COMPLETE at this time. Exceptions: • Women identified through routine prenatal screening are eligible for a maximum of two doses of varicella containing vaccine. • HCWs and Post-secondary HCW Students are eligible for a maximum of two doses of varicella containing vaccine as they present. • While Zostavax® vaccine is not indicated for and should not be used for prevention of varicella disease, it can be considered a valid first dose. This is applicable only for a first dose in a 2-dose varicella vaccine series. (Shingrix doses cannot be counted in a varicella vaccine series). **Spacing Considerations:**	

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

[1] For all HSCT recipients and SOT candidates there must be a minimum of 3 months separating 2 doses of varicella vaccine. See *Standard for Immunization of Transplant Candidates and Recipients*.

[2] 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 three months between doses.

	Varilrix®	Varivax® III
	• 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.	
Preferred Use	**Varilrix®** is the vaccine of choice for individuals with acute lymphocytic leukemia (ALL) and individuals receiving immunosuppressive treatment. For all other eligible individuals there will be no preference for the use of Varilrix® or Varivax® III in specific age or risk groups. • Both vaccines are safe and immunogenic in individuals 12 months of age and older. • Individuals with medical contraindications to one product should be offered the alternate product if supply is available.	
Dose	0.5 mL **Note:** • Withdraw the entire contents of the diluent and inject into the vial containing the powder. Once reconstituted withdraw the entire contents of the vial and inject the entire volume.	
Route	SC	
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of the vaccine including systemic hypersensitivity to neomycin. **Note:** A history of contact dermatitis to neomycin is not a contraindication. • Anaphylactic or other allergic reactions to a previous dose of a vaccine containing similar components. • Pregnancy. • Individuals with a suspicious medical history for immunodeficiency disorders until they have been investigated and T-cell dysfunction is ruled out. • Individuals with T-cell or combined T-and B-cell immunodeficiencies. • Individuals with advanced HIV. • Individuals with solid tumours. • Individuals undergoing radiotherapy. • Individuals with chronic inflammatory diseases (e.g., inflammatory bowel disease, collagen-vascular disease, nephritic syndrome) taking long-term immunosuppressive therapy or whose immunosuppressive therapy was stopped less than 6-12 weeks previously. Immunosuppressive therapy could include monoclonal antibodies (e.g. rituximab), alkylating agents, tumour necrosis factor (e.g., Enbrel), antimetabolites (e.g., methotrexate) or long-term steroids. For further information refer to: ○ Canadian Immunization Guide ○ Canada's Drug Product Database • Active, untreated tuberculosis. • Solid Organ Transplant recipients. ○ Refer to SOT Transplant Guidelines for Exceptions • Immune globulins and blood products within the previous 11 months. See Recommended Schedules Standard for Guidelines for Interval Between Immune Globulin and other Blood Products and Live Vaccines. • Varicella immunization of susceptible post-partum women should be delayed for 3 months after receipt of Rh immune globulin (RhIG).	

	Varilrix®	Varivax® III
	<u>Contraindications for Varilrix® only</u>: • Individuals undergoing immunosuppressive treatment for acute myelogenous leukemia, adults undergoing treatment for ALL and children with ALL that is not in remission (**See Considerations for Immunocompromised Individuals under Indications**). • Individuals with primary or acquired immunodeficiency states with a total lymphocyte count of less than 1,200 per mm^3 or presenting other evidence of lack of cellular immune competence, such as individuals with active leukemias, lymphomas, blood dyscrasias, clinically manifest HIV infection or patients receiving immunosuppressive therapy (including high-dose corticosteroids). **Note:** • VARILRIX® should not be administered to high-risk patients at the same time as other live attenuated vaccines (exception HIV infection see note in Schedule). **<u>Contraindications for VARIVAX® III only</u>:** • Children and adults with leukemia (ALL or acute myelogenous leukemia.) • Individuals with blood dyscrasias, leukemia, lymphomas of any type or other malignant neoplasms affecting the bone marrow or lymphatic systems. • Individuals receiving immunosuppressive therapy. • Individuals with primary and acquired immunodeficiency states including HIV infection except as outlined in Indications above. **Precautions:** • Avoid use of salicylates for 6 weeks after immunization if possible due to association of varicella and Reye syndrome. However, children and adolescents on long-term salicylate therapy should be considered for immunization with close subsequent monitoring. 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 (e.g., 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, it should be covered when possible; when not possible, direct contact with susceptible high-risk individuals (non-immune pregnant women, immunocompromised individuals, newborn infants of mothers without documented history of disease or negative serology) should be avoided for the duration of the rash.	
Possible Reactions	**Common:** • Pain, redness, swelling, pruritus, hematoma, induration, stiffness, rash/varicella-like rash and numbness at injection site • Fever • Varicella-like rash usually 5-26 days following immunization • Rash **Uncommon:** • Lymphadenopathy • Nausea, vomiting • Irritability • Headache • Fatigue, malaise, somnolence • Arthralgia, myalgia	

	Varilrix®	Varivax® III
	• Pruritus • Cough, rhinitis, and pharyngitis **Rare:** • Anaphylaxis • Urticaria • Abdominal pain, diarrhea • Conjunctivitis • Febrile seizures • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information. **Post-immunization varicella-like rash:** • Transmission from post-varicella rash to susceptible individuals is rare. Health care workers who develop a rash post-immunization should be individually evaluated. Generally, if the post-vaccine rash at the injection site can be covered, the individual can continue to work. Those with varicella-like rash not confined to the injection site should be excluded from work in high-risk patient care areas (e.g., where there are premature infants and immunocompromised patients) until the lesions are crusted.	
Pregnancy	Live vaccines are contraindicated in pregnant women. Women of child-bearing potential should be advised to avoid pregnancy for 1 month following immunization.	
Lactation	• Can be administered to eligible breastfeeding women. • If post-immunization rash develops, breastfeeding should not be discontinued. The rash should be covered if possible.	
Composition	**Each dose of 0.5 mL reconstituted vaccine contains:** • Not less than $10^{3.3}$ PFU (plaque-forming units) of varicella-zoster virus • Amino acids • Human albumin • Lactose • Neomycin sulphate • Polyalcohols • Sterile water for injection (diluent)	**Each 0.5 mL dose of reconstituted vaccine contains:** • A minimum of 1,350 PFU (plaque forming units) of Oka/Merck varicella virus • 18 mg sucrose • 8.9 mg hydrolyzed gelatin • 3.6 mg urea • 2.3 mg sodium chloride • 0.36 mg monosodium L-glutamate • 0.33 mg sodium phosphate dibasic • 57 mcg potassium phosphate monobasic • 57 mcg potassium chloride • Sterile water for injection (diluent) Residual amounts of: • MRC-5 cells (DNA and protein) • Neomycin • Fetal bovine serum from MRC-5 culture media
Blood/Blood Products	Contains human albumin as an excipient (l mg/dose).	Does not contain blood/blood products however the varicella virus is grown in MRC-5 human diploid cell culture.
Bovine/Porcine Products	• Bovine materials are used early in the manufacturing process but are not present in the final product. • No porcine products are used in the development of this vaccine.	• Contains trace quantities of fetal bovine serum from MRC-5 culture media. • Contains porcine products.
Latex	Does not contain latex.	

	Varilrix®	Varivax® III
Interchangeability	Vaccines may be used interchangeably provided the appropriate dose and schedule recommended by the manufacturer are used.	
Administration with Other Products	• Varicella vaccine can be administered simultaneously with other live vaccines or separated by an interval of at least 4 weeks. See schedule section for recommended intervals between all measles, mumps, rubella and varicella vaccines. • VARILRIX™ and VARIVAX® III can be administered at the same time as other inactivated or live vaccines using a separate needle and syringe for each vaccine. • The same limb may be used if necessary, but different sites on the limb must be chosen. • Immune globulins (IG) and antibody-containing blood products cannot be given concurrently with live vaccines and must be separated by specified time frames depending upon the dosage and the biological. Varicella vaccine should be given at least 14 days prior to administration of an IG preparation or blood product, or delayed until the antibodies in the IG preparation or blood product have degraded. If the interval between administration of vaccine and subsequent administration of an IG preparation or blood product is less than 14 days, the vaccine dose should be repeated after the recommended interval. See Recommended Schedules Standard for Guidelines for Interval Between Immune Globulin and other Blood Products and Live Vaccines. • Tuberculin skin tests should be given either before or at the same time as varicella vaccine; otherwise, the tuberculin skin test should be delayed for 4 weeks following varicella vaccine.	
Appearance	• Slightly creamy 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 $+2^0$C to $+8^0$C • Must be protected from light • Do not freeze • Do not use beyond the labeled expiry date • Diluent may be stored at room temperature • Reconstituted vaccine should be used as soon as possible. (Vaccine is unstable and begins to deteriorate as soon as reconstituted.)	
Vaccine Code	VZ	
Antigen Code	VZ	
Licensed for	Off-license use of Varilrix® has been authorized by Alberta Health for: • Children starting at 6 months of age to less than 12 months of age expecting solid organ transplant Varilrix® is licensed for all individuals outlined in the indications section.	Off-license use of Varivax® III has been authorized by Alberta Health for: • 2nd dose for children 4-6 years of age • Susceptible adults with HIV meeting clinical criteria • Children less than 12 months of age expecting solid organ transplant. Varivax® III is licensed for all other individuals as outlined in the indications section.
Program Notes: • March 2001: 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). • April 2001: A catch-up program was offered in the grade 5 school immunization program. .		

	Varilrix®	Varivax® III
• July 1, 2001: Varicella vaccine was introduced into the 12 month routine childhood immunization visit for all individuals born on or after January 1, 2000. • Spring of 2002: A catch-up program was offered during the preschool immunization visit. • April 2003: All other susceptible individuals in Alberta became eligible to receive the varicella vaccine. • August 1, 2012: 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. • September 1, 2018: Children born August 1, 2012 or later with a verbal history of chicken pox 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 two doses. • January 1, 2021: Varicella second dose offered at 18 months instead of 4 years of age.		

Related Resources:

- Varicella Vaccine Information Sheet (104508).

References:

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4. Centers for Disease Control and Prevention. (2011). General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. *Morbidity and Mortality Weekly Report, 60* (2), 36-39.
5. GlaxoSmithKline. (2019, August 14). Product Monograph. *Varilrix®: Varicella virus vaccine, live, attenuated (Oka-strain* .
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