Rotavirus Vaccine

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.315**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	June 1, 2015	**Revised**	March 3, 2025

	Rotarix	**RotaTeq**
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.
Classification	Live attenuated: replicating	Live attenuated: replicating
Indications for Provincially Funded Vaccine	Healthy infants starting immunization at 2 months up to and including 19 weeks (19 weeks 6 days) of age. • Vaccine will routinely be offered at the 2 and 4 month immunization appointments. • Healthy, non-hospitalized **preterm infants** can receive this vaccine based on their chronological age. Rotavirus vaccine may be considered for hospitalized infants in consultation with the infant's physician specialist and the Infection Control professionals in the facility.	Healthy infants starting immunization at 2 months up to and including 14 weeks (14 weeks 6 days) of age. • Vaccine will routinely be offered at the 2, 4 and 6 month immunization appointments. • Healthy, non-hospitalized **preterm infants** can receive this vaccine based on their chronological age. Rotavirus vaccine may be considered for hospitalized infants in consultation with the infant's physician specialist and the Infection Control professionals in the facility.

Schedule	**Routine Schedule:**
	Dose 1: 2 months of age
	• The first dose **must not** be administered to children who are:
	  ○ less than 6 weeks of age
	  ○ 20 weeks of age or older when starting their immunization.
	Dose 2: 4 months of age and at least 4 weeks **after** dose 1
	• Ideally the second dose should be administered by 24 weeks of age, but if immunization is delayed, the second dose must be administered **before** 8 calendar months of age.
	To determine schedule for infants expecting Solid Organ Transplant (SOT), see Immunization of Children Expecting Solid Organ Transplant.
		Routine Schedule:
		Dose 1: 2 months of age
		• The first dose **must not** be administered to children who are:
		  ○ less than 6 weeks of age
		  ○ 15 weeks of age or older when starting their immunization.
		Dose 2: 4 months of age and at least 4 weeks **after** dose 1
		Dose 3: 6 months of age and at least 4 weeks **after** dose 2. If any doses of the immunization series are delayed, the third dose must be completed **before** 8 calendar months of age, respecting the minimum interval between doses.
		To determine schedule for infants expecting Solid Organ Transplant (SOT), see Immunization of Children Expecting Solid Organ Transplant.

	Note: • To optimize protection, vaccine series should be completed by following the routine schedule as closely as possible.	

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	• If the first dose of rotavirus vaccine is inadvertently given to an infant older than the maximum age for first dose, the Medical Officer of Health (MOH)/MOH designate should be consulted. • If an incomplete dose is administered for any reason (for example, an infant spits or regurgitates the vaccine), a replacement dose should not be administered. • Infants who have had rotavirus gastroenteritis should receive or continue to receive immunization. • The rotavirus vaccine series should be completed with the same vaccine product. However, if the product used for the first dose is not available or unknown, the vaccine series should be completed with the available product. If any dose in the series was RotaTeq or is unknown, a total of three doses of vaccine should be administered. • Rotavirus vaccines may be administered concomitantly with or at any time before or after live parenteral vaccines. • Infants born to human immunodeficiency virus (HIV) positive mothers can safely receive rotavirus vaccine. The majority (greater than 99%) of these infants will not be infected with HIV. If they become infected, they do not become significantly immunocompromised until later in infancy (after rotavirus vaccine has been administered). • Infants whose mothers were taking biologics during pregnancy may be eligible to receive rotavirus vaccine. Please refer to the Summary Table in Section 2.7 of the Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression to determine eligibility.	
Preferred Use	N/A	N/A
Dose	1.5 mL	2 mL
Route	Oral For administration of rotavirus vaccine via a nasogastric tube, see Standard for the Administration of Immunizations.	
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of the vaccine or its container. • Anaphylactic or other allergic reaction to a previous dose of vaccine containing similar components. • Infants with suspected or a known immunocompromising condition, except infants born to HIV positive mothers, must have a consultation with the infant's physician specialist or expert in the condition prior to administration of the vaccine. • Uncorrected congenital malformation (for example, Meckel's diverticulum) of the gastrointestinal tract that would predispose for intussusception. • History of intussusception. • Severe Combined Immunodeficiency Disorder (SCID), a rare inherited illness which affects the immune system. • Infants with a known or suspected family history of congenital or hereditary immunodeficiency that is a contraindication to immunization with live vaccine should not receive rotavirus vaccine unless their immune competence has been established. **Precautions:** • Excretion of vaccine virus in the stools is known to occur after immunization and lasts for 10 days on average with peak excretion around the seventh day. Rotavirus vaccine may be administered to infants living in households with individuals who are immunocompromised. To minimize the risk of transmission of rotavirus vaccine virus, parents/caregivers should be counseled regarding the importance of hand washing particularly after diaper changes, before food preparation or direct contact with the immune compromised person.	

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	• No safety or efficacy data are available for the administration of rotavirus vaccine to infants who have recently received immune globulins or other blood products. However, expert opinion supports administration of rotavirus vaccine at any time before, concurrent with or after administration of immune globulins or other blood products. • Postpone vaccine administration for infants suffering from moderate or severe diarrhea or vomiting. • Infants with pre-existing chronic gastrointestinal conditions and not considered to be immunocompromised may be immunized. • Cystic Fibrosis (CF) is not a contraindication to receiving rotavirus vaccine. Screening positive at birth for CF is not a contraindication. In both scenarios rotavirus vaccine is recommended. • There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after immunization. • Infants whose mothers were taking biologics during pregnancy may be eligible to receive rotavirus vaccine. Please refer to the Summary Table in Section 2.7 of the Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression to determine eligibility. Consultation with zone MOH/MOH designate may be necessary to assess vaccine eligibility.	

Possible Reactions	**Common:**
	• Fever
	• Diarrhea and/or vomiting
	• Irritability/fussiness
	• Loss of appetite
	• Cough/runny nose
	• Otitis media
	Uncommon:
	• Bronchospasm
	• Dermatitis
	• Flatulence, abdominal pain
	• Nasopharyngitis
	Rare:
	• Anaphylaxis
	• Intussusception:
	  ○ The overall incidence of intussusception remains rare. It has not been established whether rotavirus vaccine affects the overall risk of intussusception.
	  ○ No increased risk of intussusception was observed during clinical safety trials. However, post-marketing safety studies indicate a small increased risk of intussusception after immunization, mostly within 7 days of the first dose and to a lesser extent after subsequent doses.
	  Note:
	  ▪ Parents/guardians should be informed of the low risk of intussusception following rotavirus vaccine (1 to 7 cases per 100,000 doses), particularly during the 7 days following the first and to a lesser extent subsequent doses. Parent education should include the signs and symptoms of intussusception and the importance of seeking medical care should symptoms develop. They should also be informed that the risk of intussusception remains small compared to the benefit of rotavirus vaccination in preventing disease and the potential for severe diarrhea from rotavirus.
	• As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	

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Pregnancy	This vaccine is not intended for use in adults; therefore, no human data on use during pregnancy are available and animal reproduction studies have not been performed. Infants living in households with pregnant individuals should be immunized.	
Lactation	Infants who receive human milk should be immunized.	

Composition	Each 1.5 mL dose contains:
	• $10^{6.0}$ $CCID_{50}$ of human rotavirus RIX4414 strain, produced on Vero cells.
	• Dulbecco's Modified Eagle Medium (DMEM)
	• Sucrose
	• Di-sodium adipate
	• Sterile water.
		Each 2 mL dose contains:
		• Human-bovine rotavirus reassortants G1, G2, G3, G4, and P1A[8], produced on Vero cells, with a minimum dose level at the end of shelf life as follows:
		  ○ G1 2.2 x 10^6 infectious units
		  ○ G2 2.8 x 10^6 infectious units
		  ○ G3 2.2 x 10^6 infectious units
		  ○ G4 2 x 10^6 infectious units
		  ○ P1A[8] 2.3 x10^6 infectious units
		• Sucrose
		• Sodium citrate dehydrate
		• Sodium phosphate monobasic monohydrate
		• Sodium hydroxide
		• Polysorbate 80
		• Diluent and cell culture media.

Blood/Blood Products	Does not contain any human blood/blood products.	Does not contain any human blood/blood products.
Bovine/Porcine Products	Does not contain bovine products.	**Bovine Products:** • Trace amounts of fetal bovine serum may also be present. **Porcine Products:** • DNA fragments from porcine circoviruses (PCV) 1 and 2 have been detected in RotaTeq. The source is porcine-derived material used in the manufacture of the vaccine. PCV-1 and PCV-2 are not known to cause disease in humans.
Latex	Does not contain latex.	
Interchangeability	• The rotavirus vaccine series should be completed with the same vaccine product. • If the product used for the first dose is not available or unknown, the vaccine series should be completed with the available product. • If any dose in the series was RotaTeq or is unknown, a total of 3 doses should be administered with a minimum interval of 4 weeks between doses. • For both Rotarix and RotaTeq all doses must be given before 8 calendar months of age.	
Administration with Other Products	• May be given at the same time as other inactivated vaccines. • Rotavirus vaccines may be administered concomitantly with or at any time before or after live parenteral vaccines. • Infants who have received immunoprophylaxis with RSV monoclonal antibody, for example palivizumab (Synagis), may be immunized with all routine vaccines (including rotavirus vaccine). The RSV monoclonal antibody is specific for the prevention of respiratory syncytial virus (RSV) infection and is not expected to interfere with the response to vaccines. An	

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	interval of 48 hrs is preferred for monitoring of AEFI, however vaccines may be given concurrently or at any interval before/after the RSV monoclonal antibody. • Oral poliomyelitis vaccine (OPV) should be given at least 2 weeks apart from rotavirus vaccine. OPV is not available in Canada. If historical records indicate rotavirus vaccine and OPV are given at less than 2 weeks apart, consider both vaccines as valid doses. • Rotavirus vaccine may be administered at any time before, concurrent with, or after administration of immune globulins or other blood products.	
Appearance	• A ready-to-use clear, colourless liquid, free of visible particles.	• A ready-to-use pale yellow, clear liquid that may have a pink tint.
Storage	• Store at 2°C to 8°C. • Do not freeze. • Store in the original packaging to protect from light.	
Vaccine Code	Rot	Rot-5
Antigen Code	ROT	
Licensed for	• Licensed for infants from 6 weeks of age with completion of the second dose by 24 weeks of age. • Alberta Health has approved completion of the second dose before eight calendar months of age off-license.	• Licensed for infants from 6 weeks of age with completion of the third dose by 32 weeks of age. • Alberta Health has approved completion of the third dose before eight calendar months of age off-license.
Program Notes	• 2015 June 1: Rotavirus was introduced into the routine childhood immunization schedule in Alberta using Rotarix vaccine. It was routinely offered at the 2 and 4 month immunization appointments. • 2018 May 14: RotaTeq was introduced into the routine childhood immunization schedule in Alberta. • 2021 May 1: Rotarix to replace RotaTeq for infants initiating a rotavirus vaccine series starting May 1, 2021. • 2022 August 10: RotaTeq product is not currently available in Alberta. • 2024 January 29: Added link to Standard for Chronic Conditions and/or Immunosuppression to highlight that infants whose mothers were taking biologics during pregnancy may be eligible to receive rotavirus vaccine.	
Related Resources	Rotavirus Information Sheet	

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