

# Rotavirus Vaccine

Implementation Date: January 29, 2024

## Rationale for Update:

- Added link to *Summary Table for Immunizations when on Biologics* to highlight that infants whose mothers were taking biologics during pregnancy may be eligible to receive rotavirus vaccine.

Please consult the Product Monograph <sup>1,2</sup> for further information about the vaccine.		
	<b>Rotarix®</b>	<b>RotaTeq® (not currently available)</b>
<b>Manufacturer</b>	GlaxoSmithKline Inc.	Merck Canada Inc.
<b>Licensed use</b>	Infants starting at 6 weeks of age and completion of the second dose by 24 weeks of age. <sup>1</sup>	Infants starting at 6 weeks of age and completion of third dose by 32 weeks. <sup>2</sup>
<b>Off-license use</b>	Completion of the second dose before eight calendar months of age. <sup>3,4,5</sup>	Completion of the third dose before eight calendar months of age. <sup>3,4,5,6</sup>
<b>Indications for use of provincially funded vaccine</b>	Routine program in Alberta: <ul style="list-style-type: none"> <li>Healthy infants</li> <li>Preterm infants based on chronological age who are healthy. Rotavirus vaccine may be considered for hospitalized infants, after discussion with infection control services and neonatologists.<sup>3</sup></li> </ul> <b>Note:</b> See <a href="#">Immunization for Children Expecting Solid Organ Transplant before 18 Months of Age (Accelerated)</a>	
	For infants initiating series May 1, 2021 or after.	For infants completing a RotaTeq® series that was initiated prior to May 1, 2021.
<b>Use in infants younger than 6 weeks of age and those 8 months of age and older</b>	First dose is recommended for infants starting at 6 weeks and up to 20 weeks (19 weeks 6 days) of age with series to be completed before eight calendar months of age. <sup>3,6</sup>	First dose is recommended for infants starting at 6 weeks and up to 15 weeks (14 weeks 6 days) of age with series to be completed before eight calendar months of age. <sup>3,6</sup>
<b>Dose</b>	1.5 mL	2 mL
<b>Route</b>	Oral	
<b>Schedule</b>	<ul style="list-style-type: none"> <li>❖ Dose 1: two months of age</li> <li>❖ Dose 2: four months of age</li> </ul>	<ul style="list-style-type: none"> <li>❖ Dose 1: two months of age</li> <li>❖ Dose 2: four months of age</li> <li>❖ Dose 3: six months of age</li> </ul>
	<b>Notes:</b> <ul style="list-style-type: none"> <li>The first dose of rotavirus vaccine can be administered as early as six weeks of age<sup>1,3</sup> and should not be administered to children who are delayed starting immunization if older than 19 weeks six days of age for Rotarix®.<sup>1</sup></li> <li>The first dose of rotavirus vaccine can be administered as early as six weeks of age<sup>2,3</sup> and should not be administered to children who are delayed starting immunization if older than 14 weeks six days of age for RotaTeq®.<sup>2</sup></li> </ul>	

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	<ul style="list-style-type: none"> <li>Ideally, the series should be administered by 24 weeks of age but if immunization is delayed the series must be administered before eight calendar months of age.<sup>3</sup></li> </ul>	<ul style="list-style-type: none"> <li>RotaTeq® requires 3 doses, at least 4 weeks apart.<sup>2,3</sup></li> </ul>
	<ul style="list-style-type: none"> <li>To optimize protection, vaccine series should be completed by following the routine schedule as closely as possible.<sup>3</sup></li> <li>Infants who have had rotavirus gastroenteritis should receive/continue to receive immunization.<sup>3</sup></li> <li>If an incomplete dose is administered for any reason (e.g., infant spits or regurgitates the vaccine), a replacement dose should not be administered.<sup>3,5</sup></li> <li>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.<sup>3,4,5</sup> If any dose in the series was RotaTeq® or is unknown, a total of three doses of vaccine should be administered.<sup>3,4,6</sup></li> <li>Rotavirus vaccines may be administered concomitantly with or at any time before or after live parenteral vaccines.<sup>3</sup></li> <li>Infants born to HIV positive mothers can safely receive rotavirus vaccine. The majority (&gt;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).<sup>6,7</sup></li> <li>Infants whose mothers were taking biologics during pregnancy may be eligible to receive rotavirus vaccine. Please refer to <a href="#">Immunization Recommendations for Specific Populations - Summary Table for Immunizations when on Biologics</a> to determine eligibility.<sup>9</sup></li> </ul>	
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>Known severe hypersensitivity to any vaccine components or its container.<sup>1,2,3,4</sup></li> <li>Anaphylactic or other allergic reactions to a previous dose of vaccine containing rotavirus antigens.</li> <li>Infants with suspected or known immunocompromising condition (except infants born to HIV positive mothers)<sup>6,7</sup> should not receive rotavirus vaccine without consultation with a physician specialist or expert in the condition.<sup>3</sup></li> <li>Uncorrected congenital malformation (e. g. Meckel's diverticulum) of the gastrointestinal tract that would predispose for intussusception.<sup>1,2</sup></li> <li>History of intussusception.<sup>1,2,3,4</sup></li> <li>Severe Combined Immunodeficiency Disorder (SCID).<sup>1,2,3,4</sup></li> <li>Infants with a known or suspected family history of congenital or hereditary immunodeficiency that is a contraindication to immunization with live vaccines should not receive rotavirus vaccine until their immune competence has been established.<sup>3</sup></li> </ul>	
<b>Precautions</b>	<ul style="list-style-type: none"> <li>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.<sup>1,2</sup> Rotavirus vaccine may be administered to infants living in households with individuals who are immunocompromised.<sup>3</sup> 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.<sup>1,2,3</sup></li> <li>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.</li> </ul>	

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	<p>However, expert opinion supports administration of rotavirus vaccine at any time before, concurrent with or after administration of immune globulins or other blood products.<sup>3,4,5</sup></p> <ul style="list-style-type: none"> <li>• Postpone vaccine administration for infants suffering from moderate to severe diarrhea or vomiting.<sup>1,2,3</sup></li> <li>• Infants with pre-existing chronic gastrointestinal conditions and not considered immunocompromised may be immunized.<sup>3</sup></li> <li>• 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.<sup>8</sup></li> <li>• Infants whose mothers were taking biologics during pregnancy may be eligible to receive rotavirus vaccine. Please refer to <a href="#">Immunization Recommendations for Specific Populations - Summary Table for Immunizations when on Biologics</a> to determine eligibility.<sup>9</sup></li> </ul>
<b>Possible reactions</b>	<p><b>Common:</b> Diarrhea, vomiting, irritability/fussiness, cough/runny nose, fever, loss of appetite, otitis media.<sup>1,2,3</sup></p> <p><b>Uncommon:</b> Flatulence, abdominal pain, dermatitis, nasopharyngitis and bronchospasm<sup>1,2,3</sup></p> <p><b>Rare:</b> <b>Intussusception</b></p> <ul style="list-style-type: none"> <li>• The overall incidence of intussusception remains rare.<sup>1,2</sup> It has not been established whether rotavirus vaccine affects the overall risk of intussusception.<sup>1,2,6</sup></li> <li>• 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 seven days of the first dose and, to a lesser extent the second dose.<sup>1,2,6</sup></li> </ul> <p><b>Note:</b> 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 second dose and be counseled. 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.<sup>3,6</sup></p>
<b>Pregnancy</b>	<p>Not intended for use in adults; therefore, no human data on use during pregnancy are available and animal reproduction studies have not been performed.<sup>1,2</sup></p> <p>Infants living in households with pregnant women should be immunized.<sup>3,4</sup></p>
<b>Lactation</b>	<p>Infants who are breastfed should be immunized.</p>
<b>Program Notes</b>	<ul style="list-style-type: none"> <li>• 2015 June 1 to 2018 June - Introduced into childhood schedule using Rotarix® vaccine. (Routinely offered at 2 and 4 months).</li> <li>• 2018 May 1 – RotaTeq® introduced into routine childhood immunization schedule. Rota Teq® is a three dose schedule (routinely offered at 2, 4 and 6 months) where as Rotarix® is a two dose schedule.</li> <li>• 2021 May 1 - Rotarix® to replace RotaTeq® for infants initiating a rotavirus vaccine series starting May 1, 2021.</li> <li>• 2022 July 29 - Updated to note that the RotaTeq product is not currently available in Alberta.</li> </ul>

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## References

- <sup>1</sup> GlaxoSmithKline Inc. (2018 August 2). Rotarix®: Human rotavirus, live, attenuated, oral vaccine. *Product Monograph*.
- <sup>2</sup> Merck Canada INC. (2018 January 30). RotaTeq®: Rotavirus vaccine, live, oral, pentavalent) *Product Monograph*.
- <sup>3</sup> National Advisory Committee on Immunization. (2016). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. [www.canada.ca/en/public-health/services/canadian-immunization-guide.html](http://www.canada.ca/en/public-health/services/canadian-immunization-guide.html)
- <sup>4</sup> Centers for Disease Control and Prevention. (2015). Rotavirus. In *Epidemiology and Prevention of Vaccine-Preventable Diseases 13th ed. Second Printing* (chap. 19). (Chapter updated November 3, 2020) Retrieved March 23, 2021 from, [www.cdc.gov/vaccines/pubs/pinkbook/rota.html](http://www.cdc.gov/vaccines/pubs/pinkbook/rota.html)
- <sup>5</sup> American Academy of Pediatrics, Committee of Infectious Diseases. (2018) *.Red book: 2018 Report of the Committee on Infectious Diseases* (31<sup>st</sup> ed.) Elk Grove Village, IL. : Author.
- <sup>6</sup> Le Saux, N. (2017 June 30/2018 October 23) Recommendations for the use of rotavirus vaccines in infants. Canadian Paediatric Society, Infectious Diseases and Immunization Committee Paediatric Child Health, 22(5):290-294. <https://www.cps.ca/en/documents/position/rotavirus-vaccines>
- <sup>7</sup> Expert opinion of Alberta Infectious Disease Pediatric Group February 2019.
- <sup>8</sup> Expert opinion of Cystic Fibrosis Physicians, Infectious Disease, and Medical Officer of Health. January 12, 2018.
- <sup>9</sup> Fitzpatrick, T., Alsager, K., Sadarangani, M., Pham-Huy, A., Marguía-Favela, L., Morris, S.K., Seow, C.H., Piché-Renaud, P.P., Jadavji, T., Vanderkooi, O.G., Top, K.A., Constantinescu, C. (2023). Immunological effects and safety of live rotavirus vaccination after antenatal exposure to immunomodulatory biologic agents: a prospective cohort study from the Canadian Immunization Research Network. [https://doi.org/10.1016/S2352-4642\(23\)00136-0](https://doi.org/10.1016/S2352-4642(23)00136-0)