

Updates to the Rotavirus Immunization Program: Product Change

Questions and Answers for Health Care Providers

This fact sheet provides basic information only. It must not take the place of medical advice, diagnosis or treatment. Always talk to a health care professional about any health concerns you have.

What is rotavirus disease?

Rotavirus (RV) disease is a severe dehydrating gastroenteritis, characterized by vomiting, fever, abdominal pain and watery diarrhea which may last three to eight days. In infants and young children, rotavirus infection can lead to severe dehydration.

Before the introduction of the publicly funded rotavirus immunization program, almost all children were infected by 5 years of age.

What RV vaccine products are available for use in Canada?

RV vaccine is indicated for active immunization against rotavirus gastroenteritis in infants. Two rotavirus vaccines are authorized for use in Canada.

Rot-1, Rotarix®, is a live, oral, monovalent, attenuated, human rotavirus vaccine manufactured by GlaxoSmithKline Inc.

Rot-5, RotaTeq®, is a live, oral, pentavalent rotavirus vaccine manufactured by Merck Canada Inc.

See Table 1 on page 4, for a comparison chart of both vaccines.

Are the two RV vaccine products considered equal?

The National Advisory Committee on Immunization (NACI) recommends either vaccine, without a preferential recommendation for one over the other.

Why is Ontario changing the RV vaccine product used in the publicly funded program?

Ontario participates in a federal vaccine purchasing program. During the most recent vaccine contracting process, the contract was awarded for RotaTeq®.

Who is eligible to receive the publicly funded RV vaccine in Ontario? When should the first dose of RV vaccine be administered?

All infants in Ontario are eligible for rotavirus vaccine starting as early as six weeks of age.

The Publicly Funded Immunization Schedules for Ontario recommend that the first dose of RV vaccine be administered at 2 months of age. The first vaccine dose should be administered before 15 weeks of age.

How is RV vaccine administered? What is the recommended immunization schedule for both Rotarix® and RotaTeq®?

Rotarix® is given orally as a 2-dose series, routinely at 2 and 4 months of age. The minimum interval between the first dose and second dose is 4 weeks. It can be given together with other routine infant vaccines administered at these ages.

RotaTeq® is given orally as a 3-dose series, routinely at 2, 4 and 6 months of age. The minimum interval between doses is 4 weeks. It can be given together with other routine infant vaccines administered at these ages.

What if an infant has received their first dose with Rotarix® and this product is not available for their second dose OR the product administered for the first dose is unknown?

As stated by NACI, as the two vaccines differ in composition and schedule, the

vaccine series should be started and completed with the same product, whenever possible.

If the product received for the first dose is unknown or the first dose was Rotarix® which is no longer available, complete the vaccine series with RotaTeq® for a total of 3 doses of rotavirus vaccine.

See Table 2 on page 5 for scenarios to complete a rotavirus vaccine series.

What happens if an infant spits out or regurgitates most of the RV vaccine?

Please refer to the specific product monograph for details on the rotavirus vaccine product given.

Is it safe to administer RV vaccine to infants who are breastfed?

Yes, breastfed infants can receive rotavirus vaccine.

Can premature infants receive RV vaccine?

As per the general age limits for vaccination, RV vaccines are safe and effective when administered to healthy preterm infants starting at 6 weeks of chronological age, with the first dose administered before 15 weeks of chronological age.

Who should not receive RV vaccine?

Please refer to the product monograph for details on contraindications and precautions for the specific RV vaccine.

What are the potential side effects or adverse events that could be experienced following RV vaccination?

Most infants who receive RV vaccine tolerate the vaccine well and have no side effects. However, like any medicine, side effects can occur after vaccination. Possible common reactions include diarrhea, vomiting, irritability/fussiness, cough/runny nose, fever, loss of appetite and otitis media.

Uncommon reactions include flatulence, abdominal pain, dermatitis, nasopharyngitis and bronchospasm. Based on studies and surveillance of RV vaccines there is a small increased risk of intussusception, particularly in the 7 days after the first dose.

What is the risk of intussusception following RV vaccine administration?

Intussusception in the first year of life occurs at a background rate (not associated with RV vaccination) of about 34 per 100,000 per year. The rate varies with age in the first year of life and peaks between 5 and 10 months.

Post-licensure studies of Rotarix[®] and RotaTeq[®] suggest a small increased risk of intussusception, in the range of an additional 1 to 7 cases of intussusception per 100,000 doses.

Parents should be informed of this small increased risk following RV vaccination, particularly during the 7 days following the first dose. Parents should also be counselled regarding 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

RV vaccination in preventing disease, and of the potential for severe diarrhea with RV infection.

What are the symptoms of intussusception?

Intussusception is a rare type of bowel obstruction that occurs when one portion of the bowel slides into an immediately adjacent segment (also known as telescoping or prolapse). Complications of this can lead to intestinal swelling, inflammation and decreased blood flow to the part of the intestines involved.

Symptoms of intussusception include stomach pain with severe crying (which may be brief); several episodes of vomiting; blood in the stool; or a baby may act weak or become very irritable. Intussusception is very rare.

What is the risk of transmission of the vaccine form of RV following vaccine administration?

Following vaccination, viral antigen shedding in the stool may be detected in some vaccinees, which can be from a week to several weeks. Please see the product monograph for specific vaccine details.

Transmission of the vaccine virus to household contacts can occur but is uncommon. Infants living in households with persons who have or are suspected to have immunosuppressive conditions or who are receiving immunosuppressive medications can receive rotavirus vaccine. The benefits of protecting immunocompromised household contacts from naturally occurring rotavirus by immunizing infants outweighs the very small risk of acquiring vaccine virus from vaccinated infants.

To minimize the risk of transmission of vaccine virus, caregivers should be advised to practice hand hygiene after contact with the vaccinated infant, especially after changing diapers and before food preparation or direct contact with other unvaccinated infants, pregnant women or an immunocompromised person.

Where do I find more information about the vaccines, such as common side effects, contraindications, storage recommendations and administration?

The product monograph for Rotarix® is available at: <http://ca.gsk.com/en-ca/products/rotarix/>

The product monograph for RotaTeq® is available at: <https://www.merck.ca/en/products/vaccines/>

For general information on rotavirus and vaccination, please visit the Canadian Immunization Guide at: <https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html>

Table 1: Comparison Chart for RV Vaccines Licensed for Use in Canada

	Rotarix®	RotaTeq®
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.
Authorized Use	First dose can be administered from the age of 6 weeks. Interval of at least 4 weeks between doses. Administration of the 2 doses should be completed by the age of 24 weeks.	First dose should be administered at 6 to 12 weeks of age Subsequent doses should be administered at an interval of 4 to 10 weeks between each dose, which includes a 2, 4 and 6 months immunization schedule. Completion of third dose by 32 weeks of age.
Dose	1.5 mL	2 mL
Route	Oral	Oral
Schedule	Dose 1: two months of age Dose 2: four months of age	Dose 1: two months of age Dose 2: four months of age Dose 3: six months of age

Table 2: Scenarios to Complete RV Vaccine Series

Scenario	Response
1st dose of Rotarix® was given at 2 months and Rotarix® is available	Provide 2nd dose of Rotarix® at 4 months of age – Series is complete
1st dose of Rotarix® was given at 2 months and Rotarix® is not available	Provide a 2nd dose of RotaTeq® at 4 months and a 3rd dose of RotaTeq® at 6 months of age – Series is complete
If the product is unknown for the 1st dose of rotavirus vaccine (e.g., infant arrives from out of province with an immunization record that does not specify which rotavirus vaccine was received)	Provide 2 doses of RotaTeq® at 4 and 6 months of age – Series complete