

# Rotavirus (Rotarix™) Vaccine Program

## Questions and Answers for Health Care Providers

This fact sheet provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment.

The Ministry of Health and Long-Term Care (the "ministry") is introducing a new rotavirus vaccine, Rotarix™ to the *Publicly Funded Immunization Schedules for Ontario* for protection against rotavirus infection in infants.

### About the rotavirus vaccine (Rotarix™):

**Q1:** What does the rotavirus vaccine protect against?

**A1:** The new rotavirus vaccine, Rotarix™ (human rotavirus, live, attenuated, oral vaccine), was initially licensed for use in Canada in 2007. The vaccine is indicated for active immunization against rotavirus gastroenteritis in infants caused by the G1, G2, G3, G4 and G9 serotypes which are responsible for the majority of disease in Ontario.

**Q2:** What is the age indication for the Rotarix™ vaccine?

**A2:** The Rotarix™ vaccine is a two-dose series that is approved by Health Canada for use in infants from six to 24 weeks of age. This is a live vaccine for **ORAL USE** only.

The vaccine includes an antacid component to protect the live attenuated virus during passage through the stomach and prevent its inactivation due to the acidic environment.

**Q3:** Where do I find more information about the vaccine such as common side effects, contraindications, storage recommendations and administration of the oral vaccine?

**A3:** Refer to the vaccine product monograph for Rotarix™ available at:  
[http://www.gsk.ca/english/docs-pdf/Rotarix\\_2011.pdf](http://www.gsk.ca/english/docs-pdf/Rotarix_2011.pdf)

**Q4:** How is Rotarix™ vaccine administered?

**A4:** The Rotarix™ vaccine is given as two separate 1.5 ml **oral** doses which must be separated by at least four weeks. This vaccine can be administered at the same time as other recommended routine vaccination as per the *Publicly Funded Immunization Schedules for Ontario*.

Please refer to Attachment K - *Rotarix™ (Rotavirus) Oral Administration* or the product monograph for detailed instruction regarding oral administration. **This vaccine must not be injected.**

### About the publicly funded program:

**Q5:** Why has the ministry introduced the rotavirus vaccine to the publicly funded immunization program recommended for infants?

**A5:** In July 2010, The National Advisory Committee on Immunization (NACI) recommended that all healthy infants from six weeks of age receive rotavirus vaccination. In Canada, there is a high prevalence of rotavirus gastroenteritis among children under five years

of age. In Ontario, children under two years of age face the highest burden of disease and are most likely to suffer severe complications resulting in hospitalization.

Rotavirus infection in infants and children can lead to severe dehydration, electrolyte imbalance, and metabolic acidosis. Immunocompromised children may experience severe or prolonged rotavirus gastroenteritis.

**Q6: What is rotavirus disease?**

**A6:** Rotavirus disease is a severe dehydrating gastroenteritis that occurs primarily among children aged four to 23 months, 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.

**Q7: What is the epidemiology of rotavirus in Ontario?**

**A7:** Rotavirus infection is not reportable in Ontario; therefore, the provincial burden of rotavirus disease and serotype distribution is unknown. However, Ontario studies have shown that children less than two years of age face the highest burden of disease and are most susceptible to severe complications and hospitalization.

According to limited Canadian data, it is estimated that rotavirus gastroenteritis is associated with considerable health care utilization with approximately 36% of infected children seeing a physician and approximately 15% visiting an emergency department.

**Q8: Who is eligible to receive the publicly funded rotavirus vaccine and when should they receive it?**

**A8:** Starting August 8, 2011 the ministry will offer Rotarix™ through the publicly funded program for all infants who can complete the two-dose schedule by 24 weeks of age.

The recommended routine schedule for the rotavirus oral immunization is outlined in Attachment A - **Table 1: ROUTINE** Rotavirus (Rotarix™) Immunization.

Although the vaccine manufacturer has indicated that the first dose may be administered as early as 6 weeks and as late as 20 weeks of age, NACI recommends that the first dose be

administered between 6 weeks and before 15 weeks of age as the safety of providing the first dose of rotavirus vaccine in older infants is not known. There should be a minimum of four weeks between doses. All doses should be received by 24 weeks of age.

**Q9: How effective is the vaccine?**

**A9:** The Rotarix™ vaccine has shown 85-96% efficacy against severe rotavirus gastroenteritis. During the first year after vaccination, efficacy against rotavirus gastroenteritis of any severity was around 70-87%.

**Q10: What if an infant spits out or regurgitates most of the Rotarix™ vaccine dose?**

**A10:** According to the product monograph, if an infant spits out or regurgitates most of the Rotarix™ vaccine, a single replacement dose may be given at the same vaccination visit. The infant should continue to receive any remaining doses in the recommended series.

Please refer to Attachment K - *Rotarix™ Oral Administration* or the product monograph for detailed instruction regarding oral administration.

**Q11: What are the detailed schedules for infants who have not completed or have not started their rotavirus immunization series?**

**A11:** See detailed schedules for rotavirus immunization series outlined in Attachment A - **Table 2: RECOMMENDED** vaccines and doses required to complete the rotavirus (Rotarix™) immunization series.

**Q12: Is it safe to administer rotavirus vaccine to infants who are breastfed?**

**A12:** Yes, there are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after vaccination with the rotavirus vaccine.

**Q13: What if an infant is born prematurely?**

**A13:** The rotavirus vaccine can be given to infants who were born prematurely according to their chronological age (i.e., infants who are between six and 24 weeks of age from the day they were born) as long as the pre-term infant is healthy and not hospitalized.

**Q14:** Who should not receive the rotavirus vaccine?

**A14:** Infants should not receive the vaccine if they have:

- had an allergy to a previous dose of the vaccine or any of its components;
- suspected or known immunocompromising conditions;
- "Severe Combined Immunodeficiency Disorder" (SCID);
- a history of intussusception;
- uncorrected congenital abdominal disorders (such as Meckel's diverticulum); and/or
- received blood products, including immunoglobulin, within 42 days.

Severe allergy to latex requires special consideration before vaccination.

**Q15:** What are the side effects of Rotarix™?

**A15:** Most infants who get the rotavirus vaccine do not experience any side effects. Common side effects include irritability and diarrhea. Uncommon side effects may include dermatitis, abdominal pain and/or flatulence.

Rarely, infants could experience an allergic reaction such as itchy skin rash, shortness of breath and swelling of the face or tongue. Severe reactions are very rare and may include a slight increased risk of intussusception.

**Q16:** What are the symptoms of intussusception?

**A16:** 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.

**Q17:** What is the risk of intussusception following Rotarix™?

**A17:** Studies have suggested that the Rotarix™ vaccine may be associated with a slight increased risk of intussusception in infants after they receive the vaccine, especially during the

first week. Whether Rotarix™ affects the overall incidence of intussusception has not been established.

The rotavirus vaccine offers tremendous benefits by protecting infants and children from rotavirus disease. Rotavirus is the most common cause of severe diarrhea among infants and young children. According to the United States Center for Disease Control, the risk of intussusception after rotavirus vaccination is much lower than the risk of severe rotavirus disease in unvaccinated children.

The United States Center for Disease Control continues to recommend rotavirus vaccine to prevent rotavirus disease. Post-marketing surveillance studies are ongoing.

**Q18:** What is the risk of transmission of the vaccine form of rotavirus following Rotarix™ vaccine administration?

**A18:** Following administration of the Rotarix™ vaccine, the excretion of the live attenuated vaccine virus in stool is known to occur and lasts for approximately 10 days with peak excretion around the seventh day after vaccination.

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.

**Q19:** What is the vaccine ordering process?

**A19:** Order the vaccine through your regular vaccine supply source (i.e. local public health unit or the Ontario Government Pharmaceutical and Medical Supply Service [OGPMSS]).

**Q20:** How should the rotavirus vaccine be stored?

**A20:** In order to ensure that infants receive optimal protection, the rotavirus vaccine (like other vaccines) must be maintained at a temperature between +2°C to +8°C from the time of manufacture until the vaccines are administered to the infant. The temperature must be monitored and maintained at all times.

**Q21:** What should be done for adverse events following immunization (AEFIs)?

**A21:** Similar to all other vaccines, rotavirus vaccine needs to be monitored for safety and adverse events following immunization. Physicians or other persons authorized to administer an immunizing agent are required to inform the person who consents to immunization of the importance of immediately reporting to a health care provider any reaction that may be related to the vaccine. Local public health units should subsequently be notified of the adverse event. The AEFI reporting form can be found on the

Public Health Agency of Canada website along with a User Guide at: [www.phac-aspc.gc.ca/im/ae-fi-form-eng.php](http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php) Send the completed form to your local public health unit.

A list of health units can be found at: [www.health.gov.on.ca/english/public/contact/phu/phuloc\\_mn.html](http://www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html)

## References:

1. National Advisory Committee on Immunization (NACI). Updated statement on the use of rotavirus vaccines. Can Commun Dis Rep. 2010; 36:ACS-4. Available from <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/10vol36/acs-4/index-eng.php>
2. Vaccine Product Monograph; Rotarix™, GlaxoSmithKline Inc., February 2010. [http://www.gsk.ca/english/docs-pdf/Rotarix\\_2011.pdf](http://www.gsk.ca/english/docs-pdf/Rotarix_2011.pdf)