Nova Scotia Rotavirus Vaccine Program

Information for Health Care Professionals

November 2019

Electronic copy can be found here: https://novascotia.ca/dhw/cdpc/info-for-professionals.asp

Q1. What is rotavirus disease and why is it important?

Rotavirus (RV) disease is a common cause of gastroenteritis in children caused by RNA viruses belonging to the family Reoviridae. Almost all unimmunized children are infected by 5 years of age. RV disease is characterized by vomiting, watery diarrhea, and fever. Symptoms can persist for up to 7 days. Disease is often most severe in children aged 3 months to 24 months.

In Canada, approximately 36% of children with RV gastroenteritis see a physician, 15% visit an emergency department, and 7% require hospitalization.

Q2. Who is eligible to receive publicly funded rotavirus vaccine?

RV vaccine is provided free of charge to all infants born on or after November 1, 2019.

Q3. Which vaccine is being used for this program?

Rot-5 vaccine (RotaTeq®) is used for this program. It is a live, oral, pentavalent rotavirus vaccine.

Q4. In what format will the RV vaccine be provided?

The vaccine is an oral vaccine, supplied in individual dosing tubes that allow for direct oral administration. The product is supplied in a 10-dose box.

Q5. What are the components of RV vaccine?

Each RotaTeq® single dose (2ml) contains the following active ingredients:
Human-bovine rotavirus reassortants G1, G2, G3, G4, and P1A.

Other ingredients include sucrose, sodium citrate dihydrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, diluent and cell culture media.

There are no preservatives or thimerosal present. The container and delivery system are latex-free.

For a complete list of the vaccine components, please refer to the product monograph.

Q6. What is the efficacy of the vaccine?

RV vaccine efficacy against RV diarrhea of any severity in developed world settings is 74% to 87%, and efficacy against severe diarrhea due to RV is 85% to 98%.

Q7. What is the recommended schedule for the vaccine?

Three (3) doses of vaccine are needed to complete the series, routinely at 2, 4, and 6 months of age at the same time with the other childhood vaccines. Please see the NS Routine Immunization Schedules for Children, Youth & Adults for more information.

Note: It is recommended that children be immunized as per the schedule above. The following information can assist with assessments for those immunized outside the schedule:

- Rot-5 vaccine requires 3 doses, 4 to 10 weeks apart
- The first dose of Rot-5 vaccine should not be administered before 6 weeks of age or after 15 weeks of age.
- All doses of Rot-5 vaccine should be administered before 8 months of age.

Q8. Why does the first dose of vaccine need to be given before the infant is 15 weeks?

If the child can not receive vaccine according to NS's recommended childhood schedule, the first dose of Rot-5 vaccine can be given as early as 6 weeks of age to optimize protection.

The first dose of vaccine should not be given to infants aged 15 weeks or older, as the safety of providing the first dose of Rot-5 vaccine in older infants is not known.

Q9. Why does the 3 doses need to be administered by the age of 8 months?

This age limit is related to the lack of safety data on the administration of this vaccine to older infants.

Q10. What happens if the first dose of Rot-5 vaccine is inadvertently administered at age 15 weeks or older?

If the first dose of Rot-5 vaccine is inadvertently administered to an infant older than 15 weeks, the remainder of the Rot-5 vaccine vaccination series should be completed with a minimum of 4 weeks between each dose, and all doses should be administered before 8 months of age.

Q11. If all doses cannot be administered before 8 months, should just one or two doses be given?

If a child is eligible for the first dose and presents under the age of 15 weeks, and it is known that they will not be able to receive all doses of vaccine before 8 months of age, one or two doses should be given (separated by at least 4 weeks).

Q12. Can the Rot-5 vaccine be given at the same time as other childhood vaccines? If so, is there a recommended order to give the vaccines?

Yes. The use of sweet tasting solutions is sometimes used as a pain management strategy. Due to the sucrose component in the oral Rot-5 vaccine, it may be beneficial to administer it 1-2 minutes prior to the injectable vaccines.

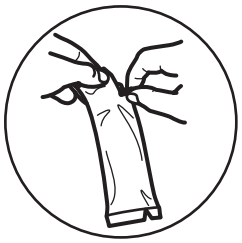
Otherwise, Rot-5 vaccine may be given at the same time as, or at any time before or after any other live or inactivated vaccine available in Canada, regardless of the route of administration of the other vaccine.

Q13. How is the vaccine administered?

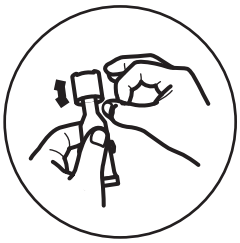
The vaccine is for oral administration only and must not be injected. It should be given under the direction of a health care provider in a clinic or office setting.

To administer the vaccine:

Tear open the pouch and remove the dosing tube.



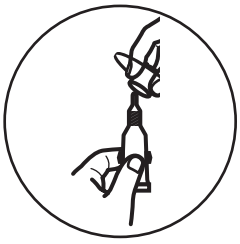
Clear the fluid from the dispensing tip by holding tube vertically and tapping cap.



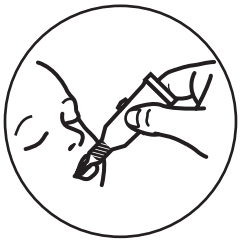
Open the dosing tube in 2 easy motions:

1
Puncture the dispensing tip by screwing cap clockwise until it becomes tight

2
Remove cap by turning it counterclockwise.



Administer dose by gently squeezing liquid into infant's mouth toward the inner cheek until dosing tube is empty. (A residual drop may remain in the tip of the tube.)



Discard the empty tube and cap in approved biological waste containers according to local regulations.

Image provided by Merck Inc.

Q14. How should I dispose of the squeezable tube after use?

Discard the empty tube and cap in a biological waste container.

Q15. Should an incomplete dose (e.g. infant spits or regurgitates the vaccine) be repeated?

No a replacement dose should NOT be administered.

Q16. What are the contraindications and precautions to receipt of the vaccine?

Prior to immunizing the RV vaccine, a pre- immunization health assessment is required.

RV vaccines are contraindicated in infants with:

- Severe Combined Immunodeficiency Disease (SCID). RV vaccine is contraindicated in infants with SCID due to a risk of severe gastroenteritis.
- a known or suspected family history of congenital or hereditary immunodeficiency that is a contraindication to vaccination with live vaccine. RV vaccine should not be administered unless their immune competence has been established;
- a previous history of intussusception;
- a history of anaphylaxis after previous administration of the vaccine; or proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container (please see product monograph for a complete list of vaccine and packaging components).

Infants known or suspected to be immunocompromised should not receive RV vaccine without consultation with a pediatric infectious disease specialist.

Infants with uncorrected congenital malformation of the gastrointestinal tract, such as Meckel's diverticulum, that would predispose the child to intussusception should not receive RV vaccine.

In infants with moderate-to-severe gastroenteritis, RV vaccine should be deferred until the condition improves unless deferral will result in scheduling of the first dose after 15 weeks of age. Infants with mild gastroenteritis can be vaccinated.

The safety and efficacy of RV vaccines has not been established in children with pre-existing, chronic gastrointestinal conditions. However, infants with chronic gastrointestinal disease who are not considered immunocompromised are likely to benefit from RV vaccine and can be vaccinated.

RV vaccines can be administered to infants with minor acute illness, with or without fever.

Q17. What are the side effects and adverse events related to the vaccine?

Most infants who receive RV vaccine tolerate it well and have no side effects. A slightly higher rate of diarrhea and vomiting in the 7 days following the receipt of the vaccine when compared to placebo was reported in a large study involving infants who received RV vaccine. Other reported side effects stated in the product monograph include fever, runny nose and sore throat, wheezing or coughing, and ear infection, allergic reactions, which may be severe (anaphylaxis), allergic swelling, hives.

Intussusception

Intussusception is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.

The risk of intussusception following RV vaccines is small based on studies that have been reviewed by the Global Advisory Committee on Vaccine Safety of the World Health Organization.

Parents should be informed of the low risk of intussusception following RV vaccine (1 to 7 cases per 100,000 doses), particularly during the 7 days following the first dose. Parents should 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 from RV.

Parent education should include the signs and symptoms of intussusception. They should be informed of the importance of seeing medical care if symptoms develop.

A pediatric infectious disease specialist referral/consultation is warranted if intussusception is suspected.

For more information regarding safety and adverse events please see the Canadian Immunization Guide.

Q18. When should I report an adverse event like intussusception?

Vaccine providers are asked to report the following adverse events following immunization (AEFI) to your local public health office:

- Intussusception in the first 21 days following any dose of RV vaccine.
- Any serious or unexpected adverse event temporally related to vaccination. An unexpected AEFI is an event that is not listed in available product information but may be due to the immunization, or a change in the frequency of a known AEFI.

Q19. How can providers obtain vaccine?

Physician offices may contact local Public Health after December 1 to order this vaccine and anytime during the year thereafter.

Q20. How should the rotavirus vaccine be stored and handled?

It must be kept refrigerated between +2°C to +8°C, protected from light, and must not be frozen.

Q21. What should I do with unused, expired vaccine?

As with other publicly funded vaccines, return expired vaccines to the nearest Public Health office.

Q22. How do I bill for the administration of this vaccine?

The fee code of this vaccine is 13.34 CCP and 6MSU. There is no tray fee for this vaccine. All other provincial immunization rules apply. Contact Medavie Blue Cross if you require further information.

References

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