

Rotavirus Oral Vaccine

Frequently Asked Questions

For Health Professionals



What is rotavirus?

Worldwide, rotaviruses are the commonest cause of community-acquired gastroenteritis in children. According to WHO estimates in 2013 about 215,000 children aged <5 years die each year from rotavirus infections; the vast majority of these children live in low-resource countries and over two million children are hospitalised each year with pronounced dehydration. Approximately 37 percent of childhood diarrhoeal deaths and 3.4 percent of all deaths in children under five are due to rotavirus infection. Children under five years of age, especially those between 6 months and two years are most vulnerable to the disease. Death from rotavirus infection is very rare in countries where there is ready access to oral and parenteral rehydration.

How safe is rotavirus oral vaccine?

Rotavirus oral vaccine has been shown to be very safe and well tolerated by the majority of babies. Over 300 million doses have been distributed worldwide.

Is the rotavirus vaccine reducing the incidence of rotavirus disease?

Rotavirus is the most common cause of gastroenteritis among infants and results in a significant number of young children being admitted to hospital each year in Ireland.

With the introduction of rotavirus vaccine to the primary immunisation schedule for all infants born on or after 1st October 2016, the number of cases of rotavirus infection reported in Ireland has fallen from 2305 cases in 2017 to 636 cases in 2018 (72%).

| Infectious Disease | 2018 | 2017 | Increase/ Decrease |
|---------------------|-------------|-------------|--------------------|
| | Week 1 - 52 | Week 1 - 52 | +/- |
| Rotavirus infection | 636 | 2305 | -1,669 |

(from HPSC)

Who should get rotavirus oral vaccine?

Rotavirus disease is prevented by vaccination. All children are offered rotavirus oral vaccine at 2 and 4 months of age.

Rotavirus oral vaccine should **not** be given to babies who are 8 months 0 days and older.

What are the contraindications to rotavirus vaccine?

- Anaphylactic reaction to a previous dose of the vaccine
- Anaphylactic reaction to any constituent of the vaccine
- A previous history of intussusception
- Severe Combined Immunodeficiency Disorder (SCID)
- A malformation of the gastrointestinal tract which might predispose them to intussusception
- A hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption.
- Age 8 months and 0 days and older.

Why is the rotavirus vaccine recommended up to 8 months and 0 days?

The SPC for Rotarix advises “The (Rotarix) vaccination course should preferably be given before 16 weeks of age, but must be completed by the age of 24 week”. However the National Immunisation Advisory Committee (NIAC) recommend “If an infant is late presenting for vaccination, they can receive their first dose of vaccine up until the age of 7 months and 0 days (Rotarix). The final dose can then be given before 8 months and 0 days”.

The National Immunisation Advisory Committee(NIAC) recommends that to provide maximum protection the first oral rotavirus vaccine (Rotarix) dose should be given by 15 weeks however if a child presents later than 15 weeks of age the child can still receive the 1st dose of the rotavirus vaccine up to the age of 7 months and 0 days and receive the second dose before 8 months and 0 days.

Each chapter of the immunisation guidelines states:

“In some circumstances, advice in these guidelines may differ from that in the Summary of Product Characteristics of the vaccines.

When this occurs, the recommendations in these guidelines, which are based on current expert advice from NIAC, should be followed”.

What is SCID and why is it relevant to rotavirus oral vaccine?

SCID is a rare inherited primary immune deficiency characterised by severe impairment in T-cell development and function. In Ireland, 1 case is diagnosed every year. It is more common in babies in some ethnic groups. The risk of an Irish infant being born with SCID is approximately 1:70,000. The risk for some ethnic groups, including Irish Travellers can be higher. Children affected by SCID can also become ill from live vaccines, including rotavirus oral vaccine. These vaccines contain viruses that are attenuated (weakened) and do not harm children with a healthy immune system. In children with SCID however, these attenuated viruses and bacteria may cause severe, life-threatening infections.

However the risk from rotavirus vaccine needs to be balanced against the risk of an infant with undiagnosed SCID contracting rotavirus disease.

How to check if the infant is at risk of SCID and what to do if they are?

Ask the infant's parent/caregiver the following questions:

- *Are there any diseases in the baby's family that affect the immune system?*
- *Did anyone in either family need a bone marrow transplant as a baby?*

If the parent/caregiver answers “No” to these questions rotavirus oral vaccine should be given.

If the parent/caregiver answers “Yes” to either of these questions:

- Check if a Full Blood Count was taken at birth and confirm the results.
- If a FBC was not taken, a full blood count with differential white cell, including lymphocyte count should be ordered.

If the lymphocyte count is below $<2.0/10^9$ litre referral to a Paediatrician should be made urgently.

Any infant at risk of SCID should NOT be given rotavirus oral vaccine or any other live vaccine.

Is a family history of autoimmune disease a contraindication to the rotavirus oral vaccine?

The question “*Are there any diseases in the baby's family that affect the immune system?*” is being asked to establish specifically if there is a family history of Severe Combined Immunodeficiency Disorder - a severe immunodeficiency (where the immune system has lost the ability to fight off infection) rather than a family history of autoimmune disease (where the immune system attacks normal tissues but still has the ability to fight infection). Therefore a family history of autoimmune disease is not a contraindication to rotavirus vaccination.

There is no need to check an FBC.

Can rotavirus vaccine be given if the infant's mother was on immunomodulatory treatment while pregnant?

The National Immunisation Advisory Committee (NIAC) advice on rotavirus vaccine and maternal immunomodulatory treatment was updated in July 2018. The guidelines now advise:

“Infants of women treated with corticosteroids in pregnancy or corticosteroids and low dose methotrexate can receive rotavirus vaccine. However if immunosuppression is anticipated to be moderate or severe, rotavirus vaccine should be deferred until the infant is 4 and 6 months of age. Moderate or major immunosuppression may occur in mothers with severe rheumatoid arthritis or inflammatory bowel disease receiving bDMARDs, and in renal transplant recipients. If in doubt, consult the supervising specialist”.

Immunomodulatory bDMARDs include:

Azathioprine, cyclophosphamide, cyclosporine, hydroxychloroquine, leflunomide, methotrexate, mycophenolic acid preparations, sirolimus and tacrolimus.

What if a household member of the babies' family is immunosuppressed (e.g. undergoing cancer treatment)?

The vaccine virus could be transmitted from the infant to severely immunocompromised contacts through faecal material for at least 14 days.

However, vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and this benefit outweighs any risk from transmission of vaccine virus to immunocompromised close contacts. All members of the household should maintain careful hand hygiene when changing an infant's nappy.

Is a family history of intussusception a contraindication to giving the rotavirus vaccine?

Intussusceptions may be idiopathic or associated with underlying diseases.

Familial occurrence of intussusception as a complication of recognizable familial underlying diseases, such as Peutz-Jeghers syndrome or cystic fibrosis, has been reported.

In those with idiopathic intussusception, familial occurrence is rare.

A family history of intussusception is not included as a contraindication or a precaution to receiving the rotavirus oral vaccine.

If an infant has a history of adoption or oocyte donation is rotavirus vaccine contraindicated?

It is very unlikely that a person with Severe Combined Immunodeficiency Disorder, hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption would donate an oocyte or sperm and if they did the information about the condition would be made known to the recipient. A history of oocyte/sperm donation or adoption is not a contraindication to the rotavirus vaccine.

Are there minimum intervals between administration of rotavirus vaccine and blood transfusion or immunoglobulin product?

No minimum interval is required between administration of a rotavirus vaccine and a blood transfusion or immunoglobulin product.

Can children with an umbilical or inguinal hernia have rotavirus vaccine?

An uncorrected or corrected umbilical or inguinal hernia are not identified as contraindications to rotavirus vaccine immunisation.

Can a child who has mild diarrhoea have the rotavirus vaccine?

Infants with mild acute gastroenteritis can be vaccinated with rotavirus vaccine, particularly if the delay in vaccination might make the infant ineligible to receive the vaccine, even though the immunogenicity and efficacy of the vaccine could be reduced. However if a child has moderate or severe vomiting or diarrhoea – the rotavirus vaccine should be deferred until the child recovers. This is to ensure that the vaccine is not passed through the intestines too quickly, which could reduce the effectiveness of the vaccine.

What if a child vomits part or all of a dose of rotavirus vaccine?

If it is judged that more rotavirus vaccine was swallowed than spat out a replacement dose of rotavirus vaccine is not necessary. If vomiting was more than 10 minutes after the vaccine was given a replacement dose of rotavirus vaccine is not necessary.

If a further dose of rotavirus vaccine is necessary the rotavirus vaccine can be given on the same day or it can be given again at any time interval after the dose that was spat out. If the child vomits out this further dose of rotavirus vaccine there is no need to attempt to give the child any further dose of the rotavirus vaccine.

The second scheduled rotavirus vaccine can be given at two months after the first dose, usually at four months of age.

Can rotavirus vaccine be given to an infant who received Palivizumab (Synagis)?

Palivizumab is a monoclonal antibody and is usually given to prevent serious infection caused by respiratory syncytial virus during the respiratory syncytial virus season. There is however no evidence that Palivizumab interferes with any vaccination and so rotavirus vaccine can be given to a child who has had or is due to receive Palivizumab.

Can the rotavirus vaccine be given after 4 months?

If an infant is late presenting for vaccination, they can receive their first dose of vaccine up until the age of 7 months and 0 days (for Rotarix). The final dose can then be given before 8 months and 0 days". The minimum recommended interval between two doses of rotavirus vaccine is 4 weeks.

Can one dose of rotavirus vaccine be given?

If an infant is late presenting for rotavirus oral vaccine, then they can receive their first dose of vaccine anytime up to the age of 7 months and 0 days. In clinical trials the effectiveness after one dose of rotavirus vaccine ranged from 51% to 60%.

What are the side effects of rotavirus oral vaccine?

The rotavirus vaccine has a very good safety profile and most side effects are mild and self limiting.

The following are side effects noted with this vaccine:

Common (1 in 10 babies)

- Diarrhoea
- Irritable

Uncommon (1 in 100 babies)

- Abdominal pain/Flatulence
- Dermatitis (skin inflammation)

Very rare (1 in 50,000)

- Intussusception
- Blood in stools
- Apnoea in very premature babies born at or before 28 weeks gestation
- Gastroenteritis in babies with SCID

As with all vaccines, there is a very rare possibility of anaphylaxis. All registered healthcare practitioners responsible for immunisation should be trained to recognise and treat anaphylaxis.

What is intussusception?

Intussusception is a condition where an infant can get a blockage in the bowel. In Ireland, approximately 1 in 1500 babies will get this condition naturally, and it is most common between the ages of 5 months and 1 year. It is thought that for every 100,000 first doses of rotavirus vaccine given, approximately two extra cases of intussusception may be seen. For Ireland, this may mean extra 1-2 cases per year of intussusception which would be related to the rotavirus vaccine. Observational safety studies indicate the increased risk of intussusception is mostly within 7 days after rotavirus vaccination.

How would I know if an infant is developing intussusception?

The main symptom of intussusception is severe abdominal pain that comes and goes. Each episode tends to last two to three minutes and the infant may draw their legs up because of the pain. In between episodes, the infant will look very pale, tired and floppy. After 12 hours or so, the pain becomes more constant and the infant will usually go off food, may vomit and have blood in their stools.

Treatment after urgent referral to hospital usually involves a non-operative procedure but on some occasions, an operation is required.

Can an infant born prematurely at < 37 weeks gestation have rotavirus vaccine?

Preterm infants are at increased risk for hospitalisation from rotavirus gastroenteritis during the first two years of life. In clinical trials, rotavirus vaccine was generally well tolerated in preterm infants, although relatively small numbers were evaluated. The benefits of rotavirus vaccination of preterm infants outweigh the risk of adverse events.

Can an infant born prematurely ≤28 weeks gestation have rotavirus vaccine?

Pre-term infants can be given the rotavirus vaccine at 2 and 4 months of age, so long as they have no other contraindications to the vaccine. Preterm infants born ≤ 28 weeks of gestation who are vaccinated while in hospital should have respiratory monitoring for 48-72 hours when given their first immunisations, particularly those with a previous history of respiratory immaturity. If the infant has apnoea, bradycardia or desaturations after the first routine immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hours. If the infant has been discharged no respiratory monitoring is necessary. Infants vaccinated whilst in hospital do not need to be isolated from other infants. As the live attenuated vaccine virus can be excreted from the infant for at least 14 days, standard infection control precautions should be followed to reduce the risk of transmission, until the vaccinated infant has been discharged.

Does the rotavirus vaccine cause Kawasaki disease?

There is no scientific evidence the rotavirus vaccine causes Kawasaki disease.

Is prolonged diarrhoea a side effect of the rotavirus vaccine?

In the studies of the Rotarix vaccine, infants developing diarrhoea was one the most common non serious adverse events for withdrawal from the studies however there was found to be no significant difference between the Rotarix and placebo groups for diarrhoea occurring after vaccination. Diarrhoea after the rotavirus vaccine should only be temporary and last a few days.

Is lactose intolerance a side effect of rotavirus vaccine?

Lactose intolerance is a disorder characterised by a lack of the enzyme lactase which normally breaks down the sugar in milk known as lactose, into simpler sugars. Rotarix contains sucrose and sorbitol as excipients and does not contain lactose. Therefore the vaccine could not cause lactose intolerance to develop. Lactose Intolerance is not described as a side effect of Rotarix vaccine.

Can rotavirus vaccine cause reflux?

Reflux is not a side effect the rotavirus vaccine. However reflux is very common in normal healthy children.

Reflux usually begins about 8 weeks of age and occurs in infants because the oesophagus is still developing

There is useful information on reflux available at mychild.ie at <http://bit.ly/2TnzoJX>

“Reflux is common and can affect up to 40% of babies. It usually occurs because a baby’s oesophagus is still developing. It generally begins around 8 weeks old and improves as they get older because the ring of muscle at the bottom of their oesophagus fully develops”.

After rotavirus vaccination, always remind parents to seek medical attention if their baby develops symptoms of intussusception.

Rotarix SPC and PIL are available at:

https://www.ema.europa.eu/documents/product-information/rotarix-epar-product-information_en.pdf

<https://www.hse.ie/eng/health/immunisation/pubinfo/pcischedule/vpds/rotavirus/>

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