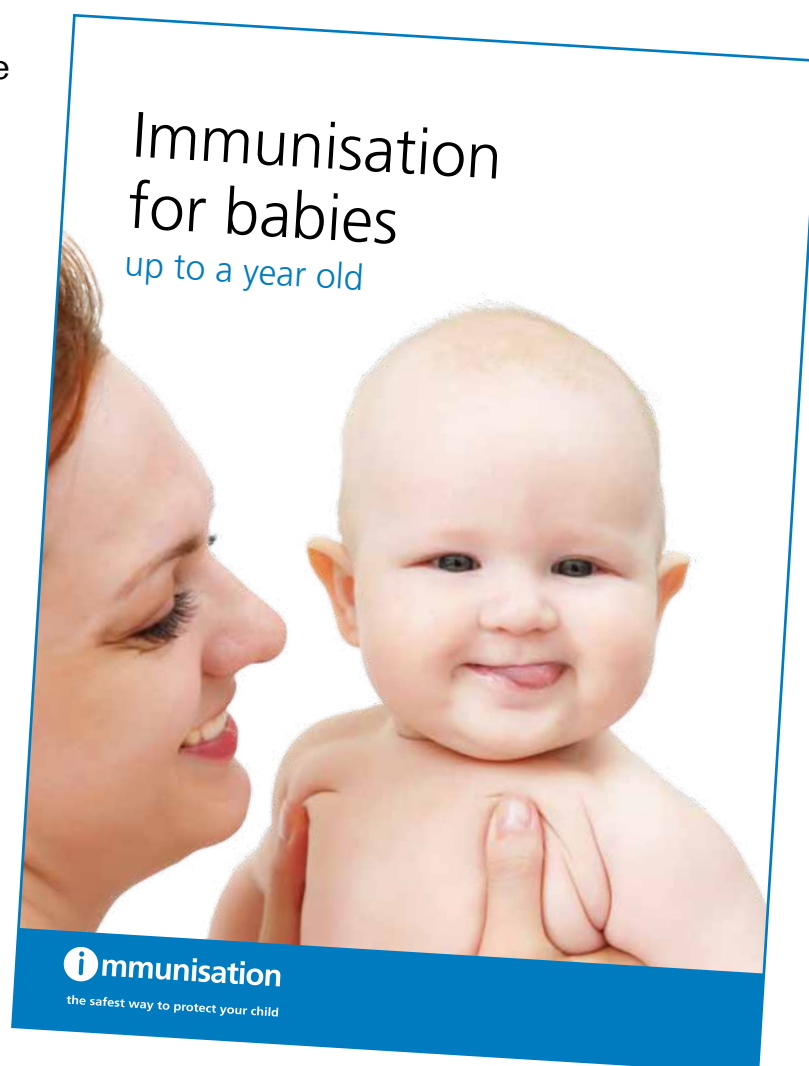


Rotavirus

Factsheet for parents

This factsheet describes the rotavirus infection and the vaccine that protects against it. It also provides the background to the development and introduction of the vaccination programme.



The disease

What is rotavirus?

Rotavirus infection is the most common cause of gastroenteritis (inflammation of the intestines) causing vomiting and diarrhoea in children under five years of age worldwide.

How common is rotavirus infection in children?

Rotavirus is a highly infectious virus. In Northern Ireland it causes around 4,000 diarrhoea cases resulting in a GP visit a year and leads to hospital stays for around 400 children.

What are the symptoms of rotavirus?

Rotavirus can cause severe diarrhoea, stomach cramps, vomiting, dehydration and mild fever. These symptoms usually last from three to eight days.

How is rotavirus spread?

Rotavirus is highly contagious and is mainly transmitted by the faecal-oral route, although respiratory transmission may also occur.

What is the most effective way of preventing rotavirus?

Apart from vaccination, good hygiene is the most important way of preventing the spread of rotavirus.

How is rotavirus treated?

There is no specific treatment for rotavirus if the child is not dehydrated and has no increased risk of dehydration. Those at risk of dehydration are advised to take an oral rehydration solution.

When should a child with rotavirus be taken to hospital?

Admission to hospital is usually recommended

if a child has signs and symptoms of severe dehydration such as:

- a decreased level of consciousness, such as appearing drowsy or unaware of their surroundings;
- pale or blotchy skin;
- cold hands and feet;
- rapid heartbeat;
- rapid breathing;
- a weak pulse.

What happens in hospital?

Treatment at hospital usually involves replacing lost fluids and other nutrients directly into a vein (intravenous fluid therapy). Most children respond well to treatment and are able to leave hospital after a few days.

Antibiotics are not used to treat rotavirus, as antibiotics are not effective against viruses.

Are there any areas of the country that are particular hotspots for rotavirus infection?

No, cases occur across the country.

Is immunity to rotavirus life-long?

Once someone has had a rotavirus infection they usually develop immunity, although it may be short-lived and infections with illness can recur.

The vaccine will protect those under one year of age who are most susceptible to serious consequences from infection. The length of immunity to vaccine or infection is not completely known; however, clinical trials have shown two doses of the vaccine to be protective for several years.

The immunisation programme

How can infants be protected against rotavirus?

Vaccination will help provide protection.

Why introduce a vaccination programme?

The Joint Committee on Vaccination and Immunisation (JCVI) – the independent experts that advise the Government on immunisation – advised that vaccinating infants against rotavirus would have a significant impact on reducing gastroenteritis, and that a vaccination programme for infants should be introduced if vaccine can be procured at a cost-effective price. The Government has established that the vaccine can be procured at a cost-effective price.

What will the impact of the programme be?

We expect to see the number of vomiting and diarrhoea cases caused by rotavirus decrease by about a half and we could see 70% fewer hospital stays for rotavirus infection in infants as a result of this vaccination programme.

When will the programme start?

The programme will start in July 2013.

When should children receive the vaccine?

The two dose course of rotavirus vaccine will be offered to infants alongside other routine immunisations when they are two and three months of age. Children over 15 weeks of age at the start of the programme will be too old to receive the vaccine.

How will the vaccine be administered?

The vaccine will be administered orally as a liquid.

How many children will be eligible for vaccination each year?

Around 25,000 infants a year in Northern Ireland will be offered the vaccine once it is introduced into the routine childhood immunisation programme.

What is the experience in other countries? Do other countries vaccinate children against rotavirus?

Yes. Many countries around the world use rotavirus vaccine as part of routine immunisation programmes. These countries have seen a reduction in severe hospitalisations as a result of rotavirus infections.

The childhood immunisation programme from July 2013

When to immunise	Diseases vaccine protects against	How it is given
2 months old	Diphtheria, tetanus, pertussis (whooping cough), polio and Hib	One injection
	Pneumococcal infection	One injection
	Rotavirus	Orally
3 months old	Diphtheria, tetanus, pertussis, polio and Hib	One injection
	Meningitis C	One injection
	Rotavirus	Orally
4 months old	Diphtheria, tetanus, pertussis, polio and Hib	One injection
	Pneumococcal infection	One injection
Just after the first birthday	Measles, mumps and rubella	One injection
	Pneumococcal infection	One injection
	Hib and meningitis C	One injection
3 years and 4 months old	Diphtheria, tetanus, pertussis and polio	One injection
	Measles, mumps and rubella	One injection
Girls 12 to 13 years old	Cervical cancer caused by human papillomavirus types 16 and 18	Three injections over six months
14 to 18 years old	Tetanus, diphtheria and polio	One injection
	Meningitis C	One injection

The vaccine

What vaccine will be used?

Rotarix®, manufactured by GlaxoSmithKline, will be the vaccine used in the routine childhood immunisation programme.

How will the vaccine be administered?

The vaccine is given orally. Two doses are given to infants at two and three months of age, and it can be given at the same time as other routine childhood vaccines.

How effective is the vaccine?

Rotarix® has been shown to protect against gastroenteritis caused by around 90% of the rotavirus strains by in circulation in the UK.

How long does the protection offered by the vaccine last?

The vaccine offers broad protection against rotavirus currently circulating as well as emerging strains, and sustains high levels of protection for several years.

Is a booster required?

No.

Is this a live vaccine?

Yes, it is a live vaccine, and contains live viruses that have been attenuated (weakened) to make them harmless to infants, but provide protection.

Is it safe?

Vaccine safety was thoroughly considered by the JCVI before it made its recommendation to vaccinate infants against rotavirus. Rotarix® has been used extensively in other countries and has a good safety record.

As they get older, some infants – about one in a thousand – get a condition that causes a blockage in their lower gut (intussusception). It is extremely rare before three months of age and most cases occur between five months and a year. Research from some countries suggests that Rotarix® may be associated with a very small increased risk of intussusception within seven days of vaccination, possibly two cases per 100,000 first doses given, and the Rotarix® prescribing information includes this as a possible side effect. To reduce the risk of this happening, the first dose of the vaccine will not be given to babies older than 15 weeks of age.

Wasn't the first rotavirus vaccine (RotaShield) removed from the market because of safety concerns?

The first generation vaccine that was introduced in the US had to be withdrawn because an association was seen between the vaccine and a small risk of developing intussusception. To date, there is no evidence suggesting a causal association between Rotarix® and the development of intussusception.

As a live virus, should close contacts take precautions?

Those in close contact with recently vaccinated infants should observe good personal hygiene.

There is a potential for transmission of live virus in Rotarix® from the infant to contacts whose immune systems are severely weakened through soiled nappies for at least 14 days (Anderson, 2008). However, vaccination of the infant will offer protection to household contacts from rotavirus disease and outweighs any risk.

What side effects may be seen from vaccination?

The most common side effects are diarrhoea and irritability. A full list of possible side effects is available in the patient information leaflet that is provided with the vaccine.

As with all vaccines, there is a very rare (approximately one in a million) possibility of this vaccine causing a severe allergic reaction called anaphylaxis. All health professionals responsible for immunisation should be trained to recognise and treat anaphylaxis.

Is the vaccine made in eggs? Does this affect children with allergies?

This vaccine is not made in eggs and should not adversely affect children with allergies, although those with a history of allergy to the vaccine or constituents of the vaccine should not be vaccinated.

Are there any reasons for the vaccine not to be given?

Vaccination should not be given to infants with:

- hypersensitivity to the active substance or to any of the ingredients;

- hypersensitivity after previous administration of rotavirus vaccines;
- a history of intussusception (a form of bowel blockage);
- uncorrected congenital malformation of the gastrointestinal tract that would predispose for intussusception;
- subjects with severe combined immunodeficiency (SCID) disorder.

Administration of Rotarix® should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection is not a contraindication for immunisation.

Administration of Rotarix® should be postponed in subjects suffering from diarrhoea or vomiting.

Does the vaccine contain thiomersal?

No.