

‘New schedule, more protection’

Frequently
Asked
Questions
for Health
Professionals



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Primary Childhood Immunisation Schedule

Children born on or after 1 October 2016

Age

Vaccination



2
months

Visit 1

6 in 1+PCV+MenB+Rotavirus
3 Injections+Oral Drops

4
months

Visit 2

6 in 1+MenB+Rotavirus
2 Injections+Oral Drops

6
months

Visit 3

6 in 1+PCV+MenC
3 Injections

No Rotavirus vaccine on or after 8 months 0 days

12
months

Visit 4

MMR+MenB
2 Injections

13
months

Visit 5

Hib/MenC+PCV
2 Injections

Remember to give your baby 3 doses of liquid infant paracetamol after the 2 and 4 month MenB vaccines.

1. Give 2.5 mls (60 mg) of liquid infant paracetamol at the time of the immunisation or shortly after.
2. Give a second dose of 2.5 mls (60 mg) 4 to 6 hours after the first dose.
3. Give a third dose of 2.5 mls (60 mg) 4 to 6 hours after the second dose.

 **Remember five visits
to your GP (doctor)**

www.immunisation.ie

Order code: HNI00984



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What are the changes to the Primary Childhood Immunisation Schedule?

The National Immunisation Advisory Committee (NIAC) in 2016 has recommended the following changes to the primary childhood immunisation schedule for babies:

- ▶ Introduction of meningococcal B (MenB) vaccine
- ▶ Introduction of rotavirus oral vaccine
- ▶ Introduction of combination Hib/MenC vaccine
- ▶ Changed timing of meningococcal C (MenC) vaccine
- ▶ Changed timing of pneumococcal conjugate vaccine (PCV)

When will the new schedule start?

All children born on or after 1st October 2016 will receive the new schedule.

The new schedule will start on 1st December 2016.

Children born before 1st October 2016 should receive the old schedule regardless of when they present for vaccination.

This means that the 2 schedules will be in place for at least 12 months.

Always check the child's date of birth to determine which schedule to give.

	Old schedule		New schedule Babies born on or after 1st October 2016	
Age (months)	Vaccine	No of injections	Vaccine	No of injections
2	6 in 1 + PCV	2	6 in 1 + PCV + MenB + Rotavirus	3 + oral vaccine
4	6 in 1 + MenC	2	6 in 1 + MenB + Rotavirus	2 + oral vaccine
6	6 in 1 + PCV	2	6 in 1 + PCV + MenC	3
12	MMR + PCV	2	MMR + MenB	2
13	MenC + Hib	2	Hib/MenC + PCV	2

As shown in the table above, the new PCI schedule has changes to the vaccines at ALL 5 visits.

By vaccine, the new schedule will be:

	Old schedule	New schedule Babies born on or after 1st October 2016
Vaccine	Age	Age
6 in 1	2, 4, 6 months	2, 4, 6 months
PCV	2, 6, 12 months	2, 6, 13 months
Men C	4, 13 months	6, 13 months
MMR	12 months	12 months
Hib	13 months	13 months
MenB	–	2, 4, 12 months
Rotavirus	–	2, 4 months

Although the timing has changed, the number of doses of PCV (3 doses) and MenC vaccine (2 doses) remains the same.

The New Vaccines

Meningococcal B Vaccine

Meningococcal Disease

What is meningococcal disease?

Meningococcal infections are caused by *Neisseria meningitidis* and include meningitis and septicaemia. Most disease-associated meningococci strains belong to serogroups A, B, C, Y or W135. *N. meningitidis* is a human-only pathogen and is carried in the nasopharynx. Approximately 10% of the population are asymptomatic carriers.

How is it transmitted?

Meningococcal bacteria can live at the back of the throat or in the nose. Most carriers of the bacteria remain well and naturally acquired serum bactericidal antibodies to *N. meningitidis* result from carriage. However, carriers can transmit the infection from person-to-person via respiratory droplets or direct mucosal contact with respiratory secretions (coughing, sneezing or kissing). It takes many hours of close personal contact to become infected as the bacteria do not survive long outside the body.

How long is the incubation period for meningococcal B disease?

A small minority of individuals who pick up *N. meningitidis* develop invasive infection after an incubation period which is typically 1-10 days, although usually less than four days.

Who is most at risk from meningococcal B disease?

Meningococcal disease may occur at any age but sporadic infection is most common in infancy and early childhood, with a second smaller peak of incidence in adolescents and young adults.

The most 'at risk' groups for invasive meningococcal B infections are:

- ▶ young age groups (incidence is highest in infants, followed by children under 5 years of age)
- ▶ active or passive smokers
- ▶ a preceding severe respiratory tract infection (particularly influenza A)
- ▶ accommodation (especially dormitory accommodation) in closed or semi-closed communities such as military barracks or halls of residence

When do most meningococcal B infections occur?

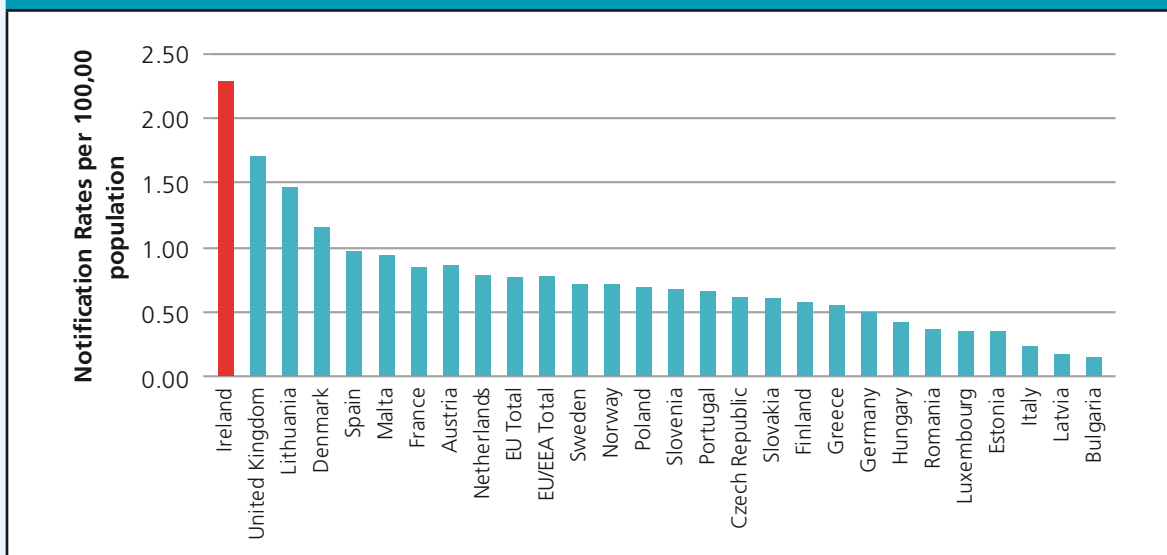
In Ireland the majority of infections occur in winter and early spring.

How many cases of meningococcal disease occur in Ireland?

Ireland has one of the highest notification rates of invasive meningococcal disease (IMD) in Europe based on confirmed cases in the EU/EEA, 2008-2012 (Figure 1).

Figure 1. Rates of IMD, EU/EEA, 2008-2012

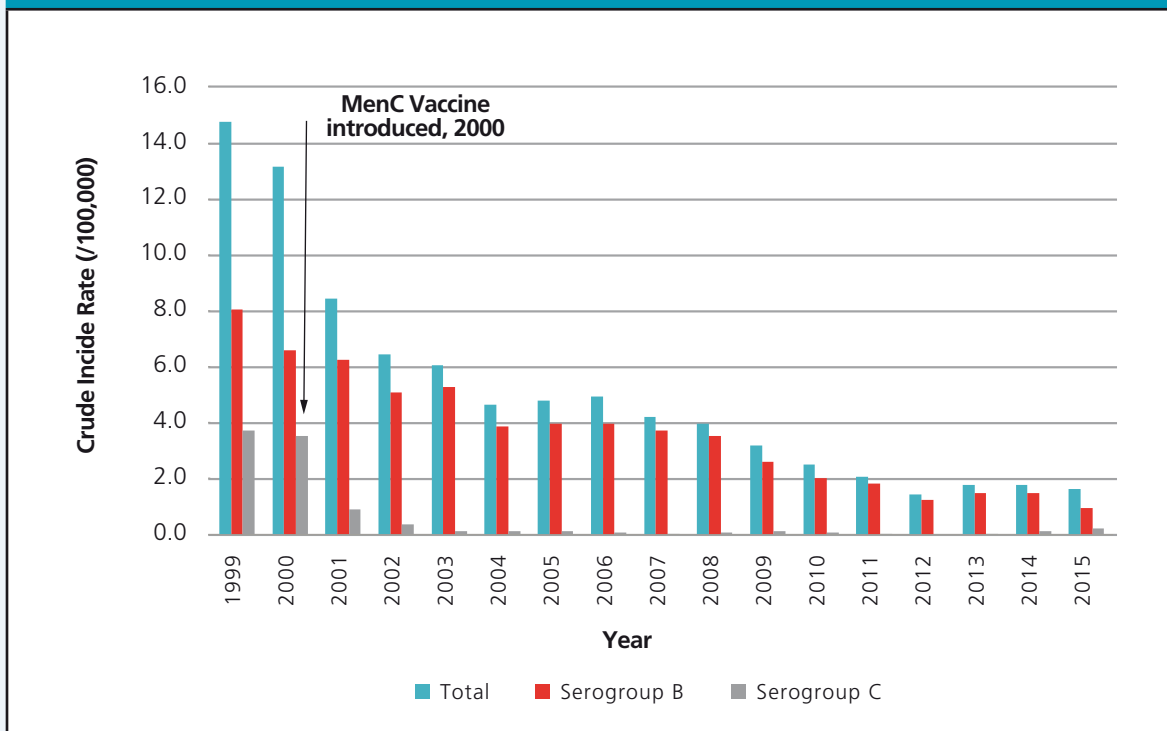
Source HPSC



Since the introduction of the meningococcal C (MenC) vaccine, meningococcal B disease has been the predominant cause of invasive meningococcal disease in Ireland (Figure 2).

Figure 2. Crude incidence rate of IMD in Ireland, 1999-2015

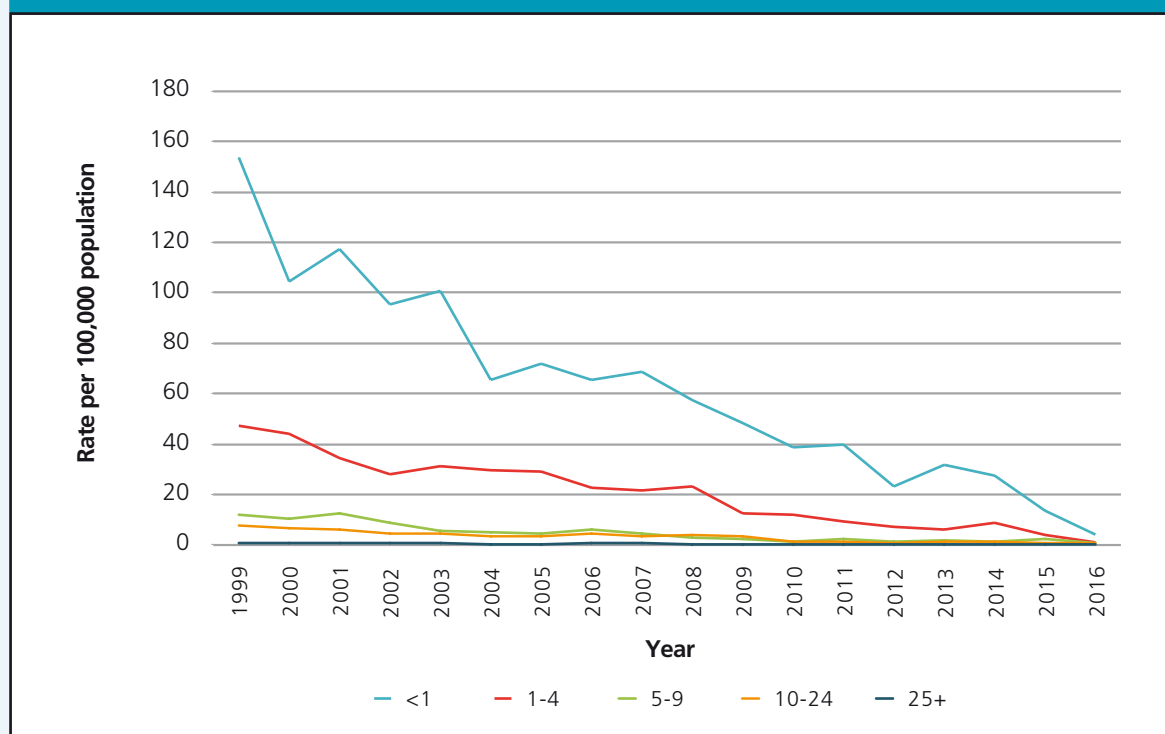
Source HPSC



In Ireland, the rate of invasive meningococcal B disease has been steadily decreasing (Figure 3). In 2015 the age specific incidence rate (ASIR) among infants, less than one year of age, for meningococcal B disease was 13.8/100,000. In the 1-4 year age group it was 3.87/100,000. The case-fatality rate from invasive meningococcal B disease is less than 5%.

Figure 3. Crude incidence rate of invasive meningococcal B disease in Ireland, 1999-2015

Source HPSC



Meningococcal B (MenB) vaccine

What is MenB vaccine?

The MenB vaccine to be used in the HSE Primary Childhood Immunisation programme (PCI) is a recombinant multi-component vaccine called Bexsero (GSK). It is **not** a live vaccine.

What does MenB vaccine protect against?

MenB vaccine protects against invasive meningococcal disease caused by *Neisseria meningitidis* group B.

Is MenB vaccine safe?

Yes. All vaccines undergo rigorous safety testing before becoming licensed for use. The vaccine was first licensed in Europe, Australia and Canada in 2013 and has been shown to be very safe and well tolerated. As with all vaccines there are some contraindications and possible side effects (see pages 7 and 8). To date 5.6 million doses have been distributed internationally.

How effective is MenB vaccine?

MenB vaccine has been shown to be very effective at producing an immune response to the particular strains of meningococcal B causing invasive meningococcal disease in Ireland. Research has suggested the MenB vaccine will provide protection from 88% of meningococcal B strains.

What is in MenB vaccine?

A full list of vaccine constituents can be found at www.hpra.ie

Does MenB vaccine contain thiomersal?

No, MenB vaccine does not contain thiomersal.

Does MenB vaccine contain porcine gelatin?

No, MenB vaccine does not contain any porcine gelatin.

Are other countries vaccinating against MenB?

There are many countries with recommendations for MenB vaccine including UK, USA, Italy, Austria and Spain. However the UK and Italy (12 regions) are the only countries offering a national funded immunisation programme for MenB vaccine, as is being provided now in Ireland.

Vaccination programme

Who should receive MenB vaccine?

All babies born on or after 1st October 2016 should be offered the vaccine as part of their Primary Childhood Immunisation (PCI) schedule at 2, 4 and 12 months of age.

How many doses of the vaccine should babies receive?

Babies should receive **three** doses in total of MenB vaccine.

When should babies receive MenB vaccine?

The three doses of vaccine should be offered to babies at the 2, 4 and 12 month PCI visits.

Can MenB vaccine be given with other vaccines?

Studies have now shown that MenB vaccine can be given at the same time as any of the other PCI vaccines.

Why is a '2+1' schedule recommended and not a '3+1' schedule as per the MenB (Bexsero) licensed information?

Studies from the UK have demonstrated that appropriate protection was provided prior to the peak incidence of invasive meningococcal disease (peak at 5 months of age) using a 2 dose primary schedule. A third booster dose at 12 months provides protection for the toddler age groups. This schedule is used in the UK and has been endorsed by the National Immunisation Advisory Committee (NIAC), in Ireland.

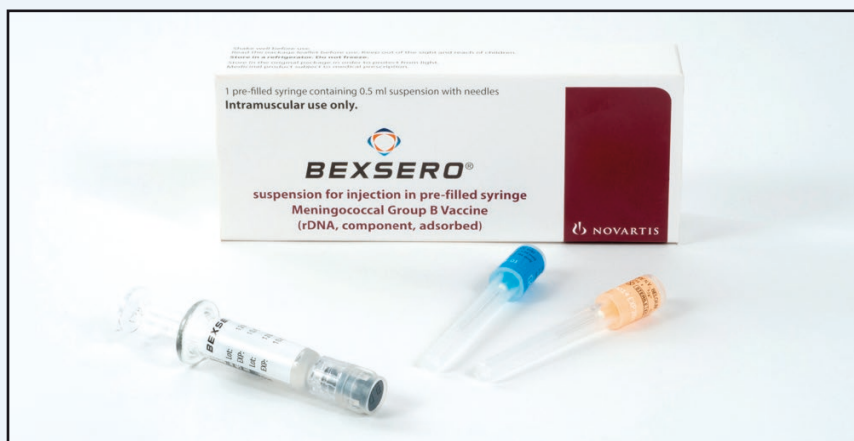
Vaccination administration

How is the vaccine presented?

Bexsero is presented as a single dose prefilled syringe with 2 needles.

The orange needle is 16mm x 25G.

The blue needle is 25mm x 23G.



In accordance with the Immunisation Guidelines for Ireland the **blue** needle should be used as the orange needle is only indicated for babies less than 2.5-3kg.

Instructions for use

- ▶ Attach blue needle.
- ▶ If a fine off white deposit is observed in the syringe, shake to dispense.

The vaccine should be a homogeneous white opalescent liquid.

How is MenB vaccine administered?

MenB vaccine is given as an intramuscular injection into the anterolateral thigh.

What order should the PCI vaccines be given?

At 2 months

Men B vaccine should be given first into the **LEFT** anterolateral thigh.

Then 6 in 1 vaccine followed by PCV should be given into the **RIGHT** anterolateral thigh.

This allows monitoring of any local adverse reactions and the most painful vaccine (PCV) is given last.

At 4 months

Men B vaccine should be given first into the **LEFT** anterolateral thigh.

Then 6 in1 vaccine should be given into the **RIGHT** anterolateral thigh.

At 12 months

Men B vaccine should be given first into the **LEFT** anterolateral thigh.

Then MMR vaccine should be given into the **RIGHT** anterolateral thigh.

What is the minimum age a baby can have the MenB vaccine?

The minimum age a baby can receive MenB vaccine is 6 weeks.

What is the minimum interval between doses of vaccine?

The minimum interval between Dose 1 and 2 is 4 weeks.

The minimum interval between Dose 2 and 3 is 8 weeks.

What if a baby is late starting the vaccine schedule?

A baby born on or after 1st October 2016 can commence the MenB vaccine schedule at any stage, after 2 months of age as per the table below.

Age	Number of doses	Schedule
2 - <10 months	3 doses	2 doses 2 months apart and booster at 12 months
10 - <12 months	2 doses	1 dose and booster at 12 months or older, 2 months after the first dose
12 months and older	2 doses	2 doses 2 months apart

There is no MenB catch-up programme for children born prior to 1st October 2016.

Exclusions and side effects

Are there any reasons why MenB vaccine should not be given?

Contraindications

- ▶ Anaphylactic reaction to a previous dose of the vaccine
- ▶ Anaphylactic reaction to any constituent of the vaccine, including kanamycin and latex.

Precautions

- ▶ In cases of acute severe febrile illness, immunisation should be deferred until the baby is well.
- ▶ If babies have a known coagulation defect, caution with administration should be taken and pressure should be applied to the vaccine site for 1-2 minutes after vaccination.

What are the side effects of MenB vaccine?

MenB vaccine is well tolerated by most babies and has a very good safety profile. The following are side effects which have been noted with this vaccine. Please see patient information leaflet (PIL) for full details available at www.hpra.ie.

Very Common (1 in 10 babies)

- ▶ Fever (>38°C)
- ▶ Tenderness/pain at injection site
- ▶ Skin rash
- ▶ Irritable
- ▶ Vomiting/diarrhoea
- ▶ Unusual crying

Uncommon (1 in 100 to 1 in 1000 babies)

- ▶ High fever (>40°C)
- ▶ Seizures (including febrile seizures)
- ▶ Eczema

Rare (1 in 1,000 to 1 in 10,000 babies)

- ▶ Urticaria
- ▶ Kawasaki's disease

Paracetamol after MenB vaccine

When MenB vaccine is given with the other PCI vaccines there is a higher risk that the baby will develop a fever.

NIAC has recommended that babies are given liquid infant paracetamol at their 2 and 4 month (MenB) vaccinations to reduce the fever.

What is the pattern of fever expected after MenB vaccine?

Fever after MenB vaccine follows a predictable pattern. The fever rises over the first 6 hours and peaks at this point. It then decreases over 24 hours, when most fevers will be gone. By 36 hours post vaccination very few babies would be expected to still have a persisting fever.

Evidence has shown that if parents are told about the possibility of fever and give paracetamol (most particularly the first dose) then very few parents medically present because of their baby's fever.

How many doses and how often should paracetamol be given?

Babies should receive 3 doses of liquid infant paracetamol (120mg/5ml) after their 2 and 4 month visits. The first dose should be given at or just after the vaccine is given. Dose 2 should be given 4-6 hours later and dose 3 should be given a further 4-6 hours after dose 2.

How much paracetamol should be given to babies?

Babies at their 2 and 4 month vaccine should receive 2.5ml (60mg) of liquid infant paracetamol.

Liquid infant paracetamol (120mg/5 ml)	2 month visit	4 month visit
Dose 1	At the time of injection	At the time of injection
Dose 2	4-6 hours after dose 1	4-6 hours after dose 1
Dose 3	4-6 hours after dose 2	4-6 hours after dose 2

What dosage of paracetamol should be given to very small babies?

If a baby weighs less than 3.5kg (7lb 7oz) at their 6-week check, the baby should be re-weighed at the time of vaccination.

If they weigh less than 4kg (8lb 8oz), paracetamol should be given at a dosage of 15mg/kg.

Will paracetamol stop babies getting a fever?

No, it reduces the rate of fever by approximately 50%. Therefore parents should be informed that their baby might still get a fever, despite giving them paracetamol. However, it is likely that it will be a lower fever and shorter lived if they give paracetamol than if they do not give paracetamol to their baby.

What if a baby still has a fever after the 3 doses of paracetamol have been given?

If the fever continues and the baby is well an additional dose of paracetamol may be given 4-6 hours after dose 3, i.e. a total of 4 doses of paracetamol in the first 24 hours after vaccination.

If the baby is unwell at any stage or has a fever (>39°C) outside of the 4 doses of liquid infant paracetamol, they should be medically reviewed.

Should paracetamol be given before vaccination?

It is important that babies are not given paracetamol prior to vaccination, as the GP or practice nurse will need to be able to assess that the baby is well to receive the vaccines.

Should paracetamol be given at the 12 month visit?

Paracetamol does **NOT** need to be routinely given at the 12 month visit for MenB vaccine, as a babies' risk of fever after the vaccine at this age is no different from the risk of fever after any other PCI vaccines.

What does the paracetamol patient information leaflet (PIL) say?

The patient information leaflet (PIL) states that babies aged 2-3 months should not be given more than 2 doses of paracetamol.

As stated in the meningococcal chapter of the Immunisation guidelines for Ireland, where advice differs from the PIL or Summary of Product Characteristics (SmPC) the recommendations based on current expert advice from NIAC should be followed.

Why has the advice about paracetamol changed?

Up until now the routine use of paracetamol for pain and fever after vaccinations was not recommended. This was because there was a study that showed a possible interference with the development of an appropriate immune response to PCV vaccine.

Further evidence has now shown that there is no evidence of a decrease in the immune response when paracetamol is given with MenB vaccine and the other primary childhood immunisations.

Should paracetamol be given to a baby who is late starting their MenB vaccines?

Paracetamol should be given when babies under 12 months receive MenB vaccine with other PCI vaccines.

Should paracetamol be given to a baby who was born before 37 weeks?

The SmPC for paracetamol states it is contraindicated to give paracetamol to babies born before 37 weeks. However, as per NIAC guidelines paracetamol can and should be given to babies born before 37 weeks using a dose correct for their weight. The dose is calculated as above for babies weighing less than 4kgs (8lb 8oz).

What should I do if a baby requires MenB vaccine at 6 or 7 weeks of age, when the SmPC for paracetamol states paracetamol should not be given to babies less than 2 months of age?

Paracetamol should be given to babies from 6 weeks of age using a dose correct for their weight. The dose is calculated as above for babies weighing less than 4kgs (8lb 8oz).

“What ifs?”

What if a baby was born prematurely?

Babies born prematurely should still receive their MenB vaccinations at the appropriate chronological age.

What if a baby has already had a confirmed meningococcal B infection?

MenB vaccine is recommended for cases of meningococcal B who have not previously received MenB vaccine.

What if a baby is immunosuppressed?

There is no contraindication to MenB vaccine in immunosuppressed babies.

Rotavirus Oral Vaccine

Rotavirus Disease

What is rotavirus?

Rotavirus is a viral infection that causes diarrhoea and vomiting in babies and young children. Whilst most babies and children will recover at home, some will become significantly dehydrated and require hospitalisation and treatment.

How is rotavirus transmitted?

Rotavirus is very infectious and can spread easily. It can be spread through hand to mouth contact, such as from touching toys, surfaces, dirty nappies or can be spread through the air from coughing and sneezing.

Who is affected by rotavirus?

Rotavirus is the most common cause of gastroenteritis in children under the age of 5 years. Symptoms last approximately 3-8 days and can include severe diarrhoea, stomach cramps, vomiting, dehydration and a low-grade fever.

When do most rotaviral infections occur?

Rotaviral infections are seasonal and peak in March, April and May.

How many cases of rotavirus occur in Ireland?

In Ireland, from 2006-2015 inclusive there was an average of 2,400 cases of rotavirus notified each year in the 0-4 years age group (Figure 4). Most of these cases are seen in the less than 1 year age group (Figure 5).

Figure 4: Number of rotavirus notifications for 0-4 years, 2006-2015

Source HPSC

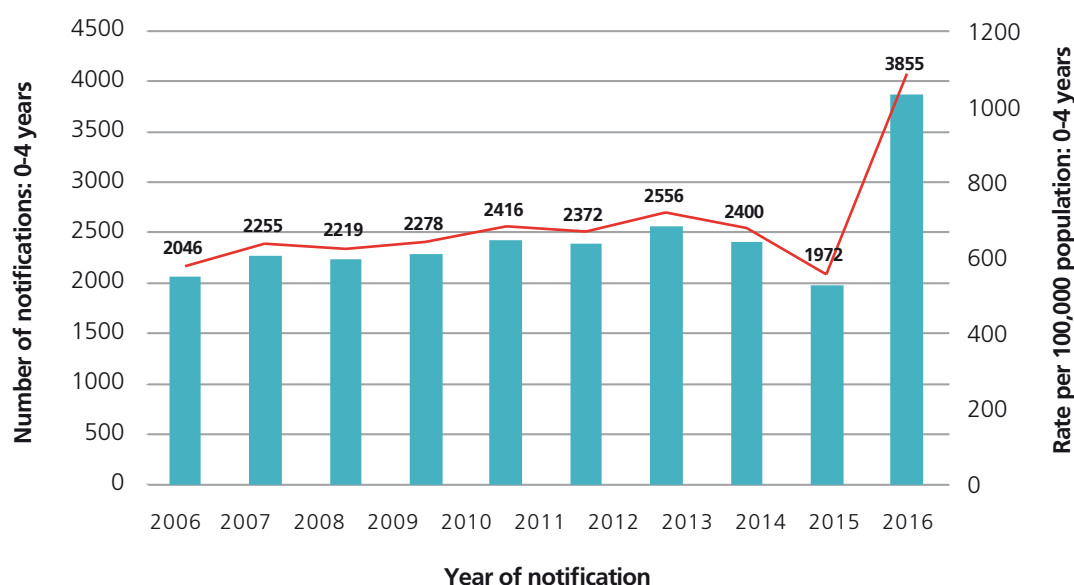
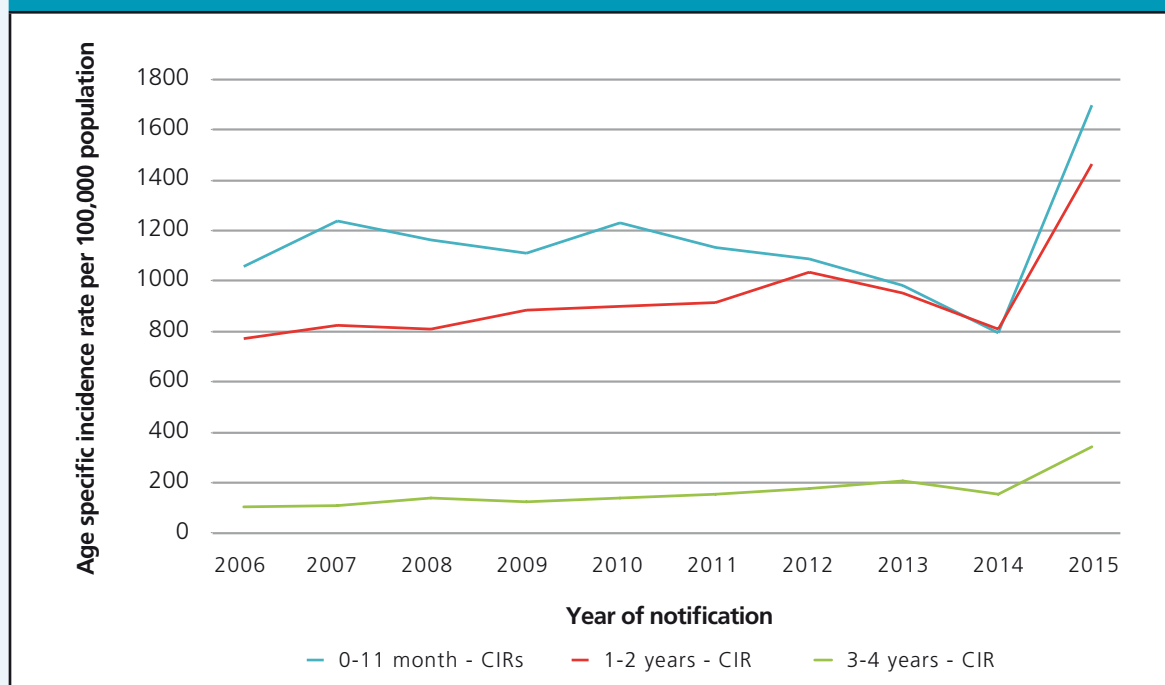


Figure 5: Age specific incidence rate per 100,000 population of notified rotavirus cases

Source HPSC



How many cases of rotavirus are hospitalised in Ireland each year?

Rotavirus accounts for a significant number of admissions to hospitals for young children. In Ireland from 2010-2014 inclusive, an average of 920 children aged 0-4 years each year were discharged from hospital with a principle diagnosis of rotaviral gastroenteritis. The average length of stay for the infection was 5 days.

Rotavirus oral vaccine

What is rotavirus oral vaccine?

Rotavirus oral vaccine is a live attenuated viral vaccine. There are two vaccines licensed for use in Ireland, one is a two dose schedule (Rotarix, GSK) and the other a three dose schedule (Rotateq, Sanofi Pasteur MSD).

The rotavirus vaccine being used as part of the PCI programme is Rotarix (GSK).

What does rotavirus oral vaccine protect against?

Rotavirus oral vaccine protects against gastrointestinal diseases caused by rotavirus infection. It will not prevent against diseases caused by other gastrointestinal viral infections, such as norovirus.

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.

As with all vaccines, there are some possible side effects and contraindications to its use (see below).

Rotavirus oral vaccine should **not** be given to babies 8 months 0 days and older. This is because of the risk that intussusception might occur in older babies given this vaccine (see page 16).

How effective is rotavirus oral vaccine?

Rotavirus oral vaccine is very effective in preventing rotavirus disease in young babies. Since the vaccine was introduced into the immunisation schedule in Australia, they have seen a 70% decline in hospitalisations due to rotavirus gastroenteritis in the under-five year's age group. Preliminary laboratory data from the UK has also identified a 70% reduction in rotavirus reports since the vaccine programme was implemented there. A European study identified a reduction in hospitalisations from rotavirus infection of between 65 to 84%. It estimated the vaccine effectiveness at between 82-94%.

What is in rotavirus oral vaccine?

Rotavirus oral vaccine is formulated in a sugary solution.

There is a plunger stopper and a protective tip cap as part of the vaccine kit. These are made of butyl rubber and should not affect those with a latex allergy. The vaccine is not formulated in eggs and therefore should not affect those with an egg allergy.

A full list of vaccine constituents can be found at www.hpra.ie

Does rotavirus oral vaccine contain thiomersal?

No, rotavirus vaccine does not contain thiomersal.

Are other countries vaccinating against rotavirus?

Yes, the World Health Organization has recommended rotavirus vaccination and many other countries are providing the vaccine to their citizens. The vaccine was licensed globally in 2006. Over 300 million doses have been distributed worldwide. Rotavirus was added to the immunisation schedule in Australia in 2007. The UK implemented a national programme in 2013. The USA and 11 other EU countries have also implemented rotavirus vaccination programmes.

Vaccination programme

Who should receive rotavirus oral vaccine?

All babies born on or after 1st October 2016 should be offered rotavirus oral vaccine at their primary childhood immunisation appointments at 2 and 4 months of age.

How many doses should babies receive?

Each baby should receive **two** oral doses of the vaccine.

When should babies receive rotavirus oral vaccine?

Babies should be offered the vaccine at their 2 and 4 month PCI visits to provide optimal protection to the baby.

Can rotavirus oral vaccine be given at the same time as other vaccines?

Yes, the vaccine can be safely given with all other vaccines provided as part of the PCI programme, or at any interval before or after the other vaccines e.g. BCG vaccine.

Vaccine Administration

How is the vaccine presented?

The vaccine comes in a box containing 10 individual vaccine doses.

The vaccine comes as a small (1.5 ml) oral suspension in a pre-filled oral applicator.

Each individual vaccine dose is ready to use and does **not** require any reconstitution.



How should the vaccine appear?

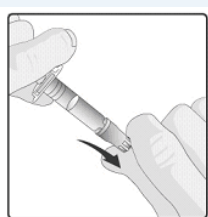
The vaccine dose should be a clear, colourless liquid with no visible particles within it. If any particulate matter is seen in the vaccine, or the vaccine appears anything other than a clear colourless liquid, the vaccine should be clearly marked 'not for use', boxed and returned to the HSE National Cold Chain Service (NCCS) when you receive your next delivery.

When should rotavirus oral vaccine be given?

The vaccine should be given at the beginning of the visit, while the baby is still content, and before administering injections. This is because the baby is likely to be most settled at the start of the vaccination schedule, which makes administering it easier. Also, the vaccine is within a sugary solution which is helpful in providing pain relief for the remaining vaccines.

How should the vaccine be given?

The vaccine is an ORAL vaccine.



STEP 1: Remove protective tip cap from the oral applicator (see diagram)

STEP 2: Ensure the baby is sitting in a reclining position.



STEP 3: Insert applicator tip into the baby's mouth, towards the inner cheek

STEP 4: Administer vaccine into the baby's mouth. The applicator containing the vaccine should be aimed down one side and towards the back of the baby's mouth. The applicator should not be inserted so far back that the baby gags. All the applicator contents should be given to the baby.

How soon before or after the vaccine can a baby feed?

A baby can feed at any stage before or after the vaccine.

What is the minimum age a baby can receive rotavirus oral vaccine?

The rotavirus vaccine can be given at any time from 6 weeks. However, the best time to receive the first dose is at 2 months of age.

What is the minimum interval between dose one and dose two of rotavirus vaccine?

The minimum interval between doses of rotavirus vaccine is 4 weeks. The recommended interval is 2 months.

What is the maximum interval between doses of rotavirus vaccine?

There is no maximum interval. However, **no rotavirus vaccine should be given to a baby after 8 months and 0 days.**

What if a baby is late starting the vaccine schedule?

If a baby is late presenting for rotavirus oral vaccine, then they can receive their first dose of vaccine anytime up to the age of 8 months and 0 days.

What if a baby is late presenting for the second dose of vaccine?

Babies can be given their second rotavirus vaccine as long as they are less than 8 months and 0 days, and there is a minimum of 4 weeks since the first dose of rotavirus vaccine.

If a baby is 8 months and 0 days of age or older then they should NOT receive any dose of rotavirus oral vaccine.

These recommendations are in line with the CDC recommendations in the USA.

Why should babies not be given rotavirus after 8 months and 0 days?

Babies are most at risk of rotavirus infections and its complications, and get best protection from the rotavirus vaccine, if they receive the vaccine at the scheduled 2 and 4 month visits. However, if they are late presenting they should still be offered the vaccine up until 8 months and 0 days. After this they should not receive the vaccine due to the slight elevated risk identified with intussusception and older babies.

Different guidelines about rotavirus oral vaccine are given elsewhere, so what guidelines should be followed?

The Rotarix SmPC states that the vaccination course should preferably be given before 16 weeks of age, but must be completed by the age of 24 weeks. In the UK, a 2 dose rotavirus oral vaccine course is given at 8 and 12 weeks of age. In the US, a 3 dose rotavirus oral vaccine course is given at 2, 4 and 6 months of age.

As stated in the rotavirus chapter of the Immunisation guidelines for Ireland, **where advice differs from PIL or SmPC the recommendations based on current expert advice from NIAC should be followed.**

Exclusions and side effects

Are there any reasons why rotavirus oral vaccine should not be given?

Contraindications

- ▶ 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
- ▶ Aged 8 months and 0 days and older.

* 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 Traveller families. The risk of an Irish infant (non-traveller) being born with SCID is approximately 1:70,000. The risk of an infant Irish traveller being born with SCID is approximately 1:1200.

If SCID is diagnosed at or shortly after birth, it can be successfully treated with a bone marrow transplant (in the UK).

SCID can result in the onset of one or more serious and even life-threatening infections within the first few months of life. These infections may include pneumonia, meningitis or septicaemia.

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 a baby with undiagnosed SCID contracting rotavirus disease.

Prior to giving rotavirus vaccine, the following questions should be asked of ALL parents to see if their baby may be at risk of SCID:

- ▶ 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 (FBC) 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 consultant paediatrician should be made urgently.

Any baby at risk of SCID should NOT be given rotavirus oral vaccine.

Precautions

Vaccination should be delayed until recovery for babies who are suffering from

- ▶ an acute febrile illness
- ▶ an acute vomiting or diarrhoea illness

What are the side effects of rotavirus oral vaccine?

The vaccine has a very good safety profile. The following are side effects noted with this vaccine and available in the PIL.

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

*** What is intussusception?**

Intussusception is a condition where a baby 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 an extra 1-2 cases per year of intussusception which would be related to the rotavirus vaccine. Intussusception can occur at any time after the vaccine is given.

How would I know if a baby is developing intussusception?

Babies with intussusception have pain similar to a severe colic, accompanied with bouts of crying. However, they generally become very pale during episodes, rather than flushed as they might with colic, and they may draw their legs up. The episodes become more frequent over a few hours associated with vomiting or blood in their stools. If this occurs then the baby needs to be urgently referred to hospital for investigation. Treatment in hospital usually involves a non-operative procedure but on some occasions, an operation is required. The sooner a baby is identified with suspected intussusception and referred to hospital, the less likely they are to need an operation.

Rotavirus vaccine should NOT be given to babies at 8 months 0 days and older because of the increased risk of intussusception.

"What ifs?"

What if a baby was given a dose of vaccine after 8 months and 0 days?

If a baby receives rotavirus oral vaccine on or after 8 months and 0 days no specific clinical monitoring needs to be performed for the baby. However, the parents should be informed about the symptoms of intussusception and the need to seek medical help if concerned.

What if a baby has received another live vaccine within the past four weeks?

There is no minimum interval of time between other live vaccines and oral rotavirus vaccine. The rotavirus vaccine can be given at any time before or after another live vaccine.

What if a baby spits out (regurgitates) rotavirus oral vaccine?

If an baby spits out or regurgitates most of the vaccine dose **at the clinic visit**, a single replacement dose should be given at the same vaccination visit.

What if a baby was born prematurely at < 37 weeks gestation?

Preterm babies 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 babies, although relatively small numbers were evaluated. The benefits of rotavirus vaccination of preterm babies outweigh the risk of adverse events.

What if a baby was born very prematurely at ≤ 28 weeks gestation?

Any preterm babies born ≤ 28 weeks who have been discharged from hospital can be given rotavirus oral vaccine.

What if a baby has already had a confirmed rotavirus vaccine infection?

Even if the baby has had a confirmed rotavirus infection, they are still recommended to receive the vaccine. This is to help protect against further episodes of infection.

What if a baby has a feeding tube in place?

Children with nasogastric feeding tubes should be given the vaccine orally, unless it is absolutely necessary to give it via the tube. Administration of rotavirus vaccine via gastrostomy is acceptable. There is no issue flushing the tube after the vaccine has been administered.

What if a baby is on anti-reflux medication?

Babies who are required to take anti-reflux medication should still receive the vaccine. The vaccine itself contains antacid to protect it from the acidic stomach environment and therefore the immune response to the vaccine should not be affected by anti-reflux medication.

What if a baby has an immunodeficiency other than SCID?

Little safety or efficacy data are available following administration of rotavirus vaccine to other babies who are immunocompromised or potentially immunocompromised. Therefore, although rotavirus vaccine strains are considerably attenuated, their administration to babies with known or suspected immunodeficiency other than SCID should be based on careful consideration of potential benefits and risks.

HIV positive babies and those of unknown HIV status should receive the rotavirus vaccine.

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

The vaccine virus could be transmitted from the baby to severely immunocompromised contacts through faecal material for at least 14 days. However, vaccination of the baby 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 hygiene when changing a baby's nappy.

What if the baby's mother was on immunomodulators while pregnant?

There is no contraindication to rotavirus oral vaccine for a baby whose mother took immunomodulators while pregnant.

What if the mother or any of the baby's carers are pregnant?

Pregnant women are more susceptible to any infections and therefore they should also ensure strict hygiene care at nappy changes to protect themselves.

Can a baby go swimming after rotavirus oral vaccine?

Yes.

No extra precautions need to be taken except usual hygiene measures should be adhered to when changing a baby's nappy. If the baby experiences diarrhoea as a side effect of the vaccine, the baby should be excluded from swimming pools for two weeks after the diarrhoea has settled.

Hib/MenC Vaccine

In the new schedule, children will receive booster doses for 3 diseases at the 13 month visit – Hib, MenC and PCV. To minimise the number of injections given to children the Hib and MenC will now be given as a combination vaccine (Hib/MenC) so that at the 13 month visit it remains a 2 injection schedule.

This vaccine will be available on the cold chain service from October 2017.

What is the Hib/Men C vaccine?

The Hib/Men C vaccine is an inactivated combination vaccine of Haemophilus influenzae type b (Hib) and Neisseria meningitidis type C. It can be given to children from 2 months of age until 10 years of age.

What Hib/Men C vaccine will be used?

The Hib/MenC vaccine which will be used is Menitorix (GSK). This vaccine is currently used in the UK childhood vaccination programme and it has been demonstrated to be both safe and effective in protecting against Haemophilus influenzae type b and meningococcal C diseases.

What is in the Hib/Men C vaccine?

The Hib/Men C vaccine contains Haemophilus influenza type b polysaccharide and Neisseria Meningitidis group C polysaccharide. The vaccine does not contain thiomersal. A full list of the vaccine constituents can be found at www.hpra.ie

Vaccination Programme

Who should receive the Hib/MenC combination vaccine?

All babies born on or after 1st October 2016 should be offered the Hib/MenC booster vaccine at 13 months of age.

Vaccination administration

How is the vaccine presented?

Menitorix comes in a single dose box. The box contains powder in a vial and a solvent for solution for injection in a pre-filled syringe with 2 needles.

1 x 21G x 40mm, 1 x 25G x 25mm.

The vaccine requires reconstitution.



Instructions for use

STEP 1: Attach green needle to syringe.

STEP 2: Insert contents of pre filled syringe into vial

STEP 3: Mix well until all the powder is dissolved

STEP 4: Draw vial contents back into the syringe

STEP 5: Change to blue needle and administer

How should the vaccine appear?

Once reconstituted the powder dissolves and appears as a clear, colourless liquid with no visible particles within it. If any particulate matter is seen in the vaccine, or the vaccine appears anything other than a clear, colourless liquid, then the vaccine should be clearly marked 'not for use', boxed and returned to the HSE National Cold Chain Service (NCCS) when you receive your next delivery.

How should the vaccine be given?

Hib/MenC vaccine is given as an intramuscular injection into the anterolateral thigh or deltoid as per any other childhood vaccine.

Can the vaccine be given at the same time as other vaccines?

Yes, the vaccine can be safely given with all other vaccines provided as part of the HSE PCI programme.

Exclusions and side effects

Are there any reasons why Hib/MenC should not be given?

Contraindications

- ▶ Anaphylactic reaction to the Hib/MenC vaccine; any Hib or MenC vaccine or tetanus toxoid.
- ▶ Anaphylactic reaction to any of the constituents of the Hib/MenC vaccine

Precautions

- ▶ Vaccination should be delayed until recovery for babies who are suffering from an acute febrile illness.
- ▶ If babies have known coagulation defects, caution with administration should be taken and pressure should be applied to the vaccine site for 1-2 minutes after administration.

What are the side effects of Hib/MenC vaccine?

The vaccine has a very good safety profile. The following are side effects noted with this vaccine and available in the PIL at www.hpra.ie.

Very Common	Uncommon	Rare
(1 in 10 babies)	(1 in 100 babies)	(1 in 1,000 babies)
Pain at injection site	Crying	Abdominal pain
Fever	Diarrhoea	Sleepiness
Irritability	Sickness	Generally feeling unwell
Loss of appetite	Fever	
Sleepiness	Rash	

"What ifs?"

What if I give the Hib/MenC in error at the 6 month visit?

The Hib/MenC vaccine can be given as part of the primary protection from Haemophilus influenzae type b and Meningococcal C disease. If the Hib/MenC vaccine is given in error at 6 months then no single MenC vaccine will be required at this time. The baby will have received Hib as part of their third 6in1 vaccine. No cases of overdose have been reported with the Hib/MenC vaccine, or Hib components of vaccines. The baby should continue with vaccines at appropriate ages as recommended in the routine PCI schedule.

Other Changes

PCV Vaccine

The PCV vaccine schedule will change from 2, 6 and 12 months to 2, 6 and 13 months. This is to facilitate the introduction of MenB booster vaccine at 12 months. Meningococcal B disease has a higher age-specific incidence in this age group and therefore this booster dose is provided as early as possible.

MenC vaccine

The MenC vaccine schedule will change from 4 and 13 months to 6 and 13 months. This is to facilitate MenB vaccine at 2 and 4 months of age. Since the successful introduction of the MenC vaccine in 2000, the age-specific incidence amongst this age group has decreased significantly. Meningococcal B disease has a higher age-specific incidence in this population and therefore protection with MenB vaccine is provided at the earliest age.

Vaccine ordering and storage

MenB vaccine

How can MenB vaccine be ordered?

MenB vaccine can be ordered from the HSE National Cold Chain Service (NCCS) using the same online procedure used for all other PCI vaccines. See <https://www.ordervaccines.ie/login.aspx>

The amount of MenB vaccine you can order will be set based on your previous PCI vaccine usage.

If you need to order more please contact vaccines@udd.ie

How should MenB vaccine be stored?

The vaccine should be stored in a pharmaceutical fridge which maintains temperature between +2°C and +8°C.

Rotavirus oral vaccine

How can rotavirus oral vaccine be ordered?

Rotavirus oral vaccine can be ordered from the HSE National Cold Chain Service (NCCS) using the same online procedure used for all other PCI vaccines. See <https://www.ordervaccines.ie/login.aspx>

The amount of rotavirus oral vaccine you can order will be set based on your previous PCI vaccine usage.

If you need to order more please contact vaccines@udd.ie

How should rotavirus oral vaccine be stored?

The vaccine should be appropriately stored in a pharmaceutical fridge which maintains temperature between +2°C and +8°C.

How should the rotavirus oral vaccine be disposed of?

Used vaccine equipment should be disposed in an appropriate clinical waste bin. As the vaccine **IS NOT INJECTED** disposal in a sharps bin is not necessary.

Hib/MenC vaccine

How can Hib/MenC vaccine be ordered?

Hib/MenC vaccine can be ordered from the HSE National Cold Chain Service (NCCS) using the same online procedure used for all other PCI vaccines. See <https://www.ordervaccines.ie/login.aspx>

The amount of Hib/MenC vaccine you can order will be set based on your previous PCI vaccine usage.

If you need to order more please contact vaccines@udd.ie

Hib/MenC vaccine will be available to order from October 2017.

How should Hib/MenC vaccine be stored?

The vaccine should be stored in a pharmaceutical fridge which maintains temperature between +2°C and +8°C.

Published by: HSE National Immunisation Office

Publication date: October 2016



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

