Meningococcal B immunisation programme

Factsheet for healthcare professionals

Background

In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) recommended the introduction of a routine infant meningococcal B immunisation programme. The current immunisation programme as of 1 July 2025 consists of a 2+1 schedule at 8 and 12 weeks with a booster at 1st birthday. The purpose of the immunisation programme is to reduce the burden and severity of invasive meningococcal disease (IMD) caused by *Neisseria meningitidis* capsular B in the UK by protecting those who are at increased risk of disease.

What is meningococcal disease?

Meningococcal disease is caused by invasive infection with the bacterium *Neisseria meningitidis*, also known as meningococcus. The bacteria commonly colonises the nasopharynx of humans without causing invasive disease and 5-11% adults and up to 25% of adolescents are asymptomatic carriers of the bacteria. Meningococci can be transmitted by respiratory aerosols, droplets or by direct contact with the respiratory secretions of someone carrying the bacteria. Twelve different capsular types of the bacteria have been identified and Group B has been responsible for the majority of laboratory confirmed cases in the United Kingdom. In Northern Ireland, there were just under 30 cases of invasive meningococcal disease notified in 2023, 24 of which were laboratory confirmed and 19 confirmed as capsular Group B (5 cases untyped). Invasive meningococcal disease most commonly causes either meningitis, septicaemia or a combination of both. The incubation period is two to seven days and clinical presentation ranges from severe, acute and overwhelming features to mild prodromal symptoms.

Who is affected by meningococcal disease?

Meningococcal disease can affect all age groups but rates of disease are highest in children under two years of age. The number of cases increases from birth and, following the introduction of the MenB vaccination programme, peaks at 2 to 3 months before declining gradually until 24 months. However, since the introduction of the MenB vaccination programme (when vaccination was initially offered at 8 and 16 weeks of age), the peak age of infection has shifted from 5 to 6 months to 1 to 3 months of age, with a substantial proportion of cases occurring before infants have gained protection from the second dose of vaccine. Cases of meningococcal disease remain low until 12 years of age and then gradually increase to a smaller peak at 18 years before declining again.

Individuals with asplenia, splenic dysfunction or complement disorders are also at increased risk of invasive meningococcal disease and should be immunised in accordance with the schedule for immunisation of individuals with underlying medical conditions: green book chapter 7.

Who is the vaccine recommended for?

It is recommended that the first two doses of MenB vaccine are administered with the other primary immunisations at 8 weeks and 12 weeks and that the third dose is given on or after the first birthday (2+1 schedule).

All infants are eligible for the meningococcal B vaccine up until they are 2 years of age.

For children presenting late for vaccination, please refer to the Vaccination of individuals with uncertain or incomplete immunisation status algorithm from UK Health Security Agency (UKHSA).
https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status

What is the recommended vaccine for the programme?

Bexsero® is the recommended vaccine for the routine infant immunisation programme and is the **only** market authorised meningococcal B vaccine in the UK. This vaccine is a multi-component inactivated vaccine made from three *Neisseria meningitidis* proteins produced by recombinant DNA technology (*Neisseria meningitidis* group B NHBA fusion protein, *Neisseria meningitides* group B NadA protein, *Neisseria meningitidis* group B fHbp fusion protein) and a preparation of *Neisseria meningitidis* capsular group B outer membrane vesicle (OMV) *Neisseria meningitidis* group B strain NZ98/254).

Vaccine eligibility for the routine meningococcal B immunisation programme

Why is the national programme being routinely offered to infants aged 8 and 12 weeks?

Meningococcal disease can affect all age groups, but the rates of disease are highest in the first two years of life. Cases increase from birth and peak around 2 to 3 months before declining. In considering the epidemiological and economic evidence as well as vaccine safety and efficacy, the JCVI decided to prioritise young infants with the aim of providing optimal protection as early as possible.

How is the programme delivered?

Bexsero® is available through General Practice (GP) services. Parents attending their GP practice for their child's routine primary immunisations at 8 and 12 weeks of age will be offered meningococcal B vaccine.

How effective is the vaccine?

Bexsero® has been shown to be immunogenic in infants and toddlers. Vaccine-induced antibodies have been shown to be bactericidal (ie they kill the bacteria) against most meningococcal strains causing invasive disease in the UK. The effectiveness of MenB vaccine was assessed in a national observational cohort study completed by Public Health England following the introduction of MenB vaccine to the routine schedule in September 2015. The two-dose priming schedule was highly effective in preventing MenB disease in infants and the cases of MenB in vaccine eligible infants in England halved in the first 10 months of the programme. The vaccine was shown to be 82.9% effective in preventing MenB disease in infants. We have seen a similar reduction in cases of MenB in vaccine eligible infants in Northern Ireland.

How many doses are required to ensure protection?

Clinical trials for Bexsero® in infants initially included three doses followed by a booster in the second year of life. Recent studies, however, indicate that two Bexsero® doses given one month apart at 8 and 12 weeks of age will induce bactericidal antibodies against meningococcus group B in nearly all infants. Vaccine responses will also be boosted after the 12-13 month dose given when turning 1 year old.

Due to the changing epidemiology of IMD, the JCVI agreed that it would be beneficial to move the second dose of MenB vaccine to 12 weeks of age to provide earlier protection. Recent evidence from the (as yet unpublished) LION MenB randomised control trial showed that a good response was made when two doses of MenB vaccine were given four weeks apart at 8 and 12 weeks of age.

To avoid increasing the number of injections at the 12 week appointment, the first dose of PCV13 will be moved to the 16 week appointment. Offering the MenB vaccine at 8 and 12 weeks and the PCV13 vaccine at 16 weeks is also associated with an improved safety profile over the previous schedule for these vaccines. In the LION MenB study, giving this schedule was associated with a lower rate of local and systemic adverse effects.

Summary of changes to the schedule from 1 July 2025

From 1 July 2025, the second MenB dose will be brought forward from 16 weeks of age to 12 weeks of age and the first PCV dose will move from 12 weeks of age to 16 weeks of age:

- infants who have not yet received their 12 week vaccinations by 1 July 2025, should be vaccinated as per the new schedule timings (second MenB at 12 weeks and PCV13 at 16 weeks);
- infants who have already received their 12-week PCV13 vaccination prior to 1 July 2025 should remain on the previous schedule and be invited for their second MenB vaccine at 16 weeks of age.

Although previously, an 8-week minimum interval between doses of MenB vaccine was recommended, a recent study (LION MenB) has shown that a 4-week interval between doses provides a similar immune response to an 8-week interval. Data on reactogenicity has also been shown to be more favourable when a four-week interval is used.

How long does protection last for?

The duration of protection following the recommended routine Bexsero® schedule has not been established, although in reviewing all of the available evidence, the JCVI agreed the most plausible duration of protection is 18 months following a two dose primary course and 36 months following the additional booster dose administered at 12 months. Bexsero® should, therefore, help protect infants and toddlers during their period of highest risk of meningococcal B infection. The schedule change to 8 and 12 weeks has the potential for preventing some of the remaining cases of invasive meningococcal disease in infants who have not yet received their full primary course by providing infants with earlier protection against meningococcal disease.

Does Bexsero® provide cross protection against other meningococcal capsular groups, such as Men A, C, W and Y?

Whilst Bexsero® has broad coverage against most MenB strains causing IMD in the UK, it does not offer complete protection. However, it can offer protection against some non-MenB strains because it is not targeting the outer polysaccharide that is group specific.

However, it is important that individuals requiring protection against meningococcal serogroups A, C, W and Y should receive the MenACWY conjugate vaccine and should not be assumed to be protected against these capsular groups even if they have received a complete course of Bexsero®.

Can the vaccine be offered to infants outside of the national programme?

GPs can, based on their clinical judgement, write a HS21 prescription for the MenB vaccine for those who are not eligible under the childhood vaccination programme. Clinical judgement should take into account the recommendations of JCVI as published in the Green Book. Information about patients who should be offered MenB and who are not part of the routine cohort are provided in chapter 7 of the Green Book and include patients with asplenia, splenic dysfunction and complement disorders.

JCVI have advised that it is not cost-effective for NHS to offer vaccination to older children who are not in the routine cohort. If a parent requests MenB vaccine for their child and the GP does not feel that it is appropriate, the vaccine can only be given under a private arrangement. Under contract regulations GPs cannot write private prescriptions for their own patients.

What are the contraindications for receiving Bexsero®?

There are very few infants who cannot receive meningococcal vaccines. Where there is doubt, instead of withholding immunisation, appropriate advice should be sought from a consultant paediatrician with immunisation expertise, a member of the local immunisation team or from PHA Health Protection Duty Room (Tel: 0300 555 0119).

Bexsero® should **not** be administered to those who have had:

1. A confirmed anaphylaxis to a previous dose of the vaccine OR
2. A confirmed anaphylaxis to any constituent or excipient of the vaccine

For the composition and full list of excipients of the vaccine, please refer to the manufacturer's Summary of Product Characteristics (SPCm).

What adverse reactions are commonly associated with the administration of Bexsero®?

In clinical vaccine trials, the **most common adverse reaction** observed in infants and children under two years of age was a high rate of fever (>38°C) when Bexsero® was administered with the other routine childhood vaccines (see below).
Other **very common** (occur in more than 1 in 10 children) adverse reactions observed in infants and children (up to the age of 10 years) are tenderness at the injection site (including severe tenderness defined as crying when moving injected limb), rash, swelling or induration at the injection site, irritability, change in feeding/eating, sleepiness and unusual crying.

All suspected adverse reactions should be reported to the MHRA using the Yellow Card scheme.

The manufacturers Summary of Products Characteristics (SPCm) states that infants were at an increased risk of fever when Bexsero® was administered at the same time as other routine childhood vaccines.

How common is fever after vaccination with Men B and can it be prevented?

In one clinical trial, fever (>38°C) was reported in 51-62% of infants receiving Bexsero® and routine vaccines administered together, although high fever (>39°C) was less common (6-12%). Overall, fever (>38°C) after any vaccination was reported in 76% of infants receiving Bexsero® and routine vaccines together, compared to 51% in infants receiving the routine vaccinations alone. In that study, however, only six of the 1,885 recruited infants attended the hospital because of fever within two days after vaccination with Bexsero®.

In a subsequent study, 70% of infants receiving Bexsero® had fever >38.5°C at least once in the first three days after any primary dose. However, fever was less common (39%) in infants receiving prophylactic paracetamol just before or at the time of vaccination followed by two further administrations at four to six hour intervals after vaccination by parents/guardians. Of note, only ~5% of infants receiving paracetamol had fever >39°C and the frequency of medically-attended fever within three days of vaccination was <2% for any vaccination visit, irrespective of whether the Bexsero® was administered alone or together with the routine vaccinations.

The latter study was also important because it showed that responses to Bexsero® and the routine vaccinations were not affected by administering prophylactic paracetamol at the time of vaccination.

In another vaccine study that did not include Bexsero®, infants receiving three doses of paracetamol (at vaccination and at 6-8 hour intervals) were half as likely to develop any post-vaccination fever, and also half as likely to develop high fever (>39°C), compared with infants receiving two doses of paracetamol (first dose at 6-8 hours after vaccination and another 6-8 hours later). Thus, the greatest benefit in reducing post-vaccination fever appears to come from the paracetamol dose given around the time of vaccination.

For the Bexsero® programme, the JCVI has recommended three doses of paracetamol to be given to infants receiving Bexsero® with their routine primary immunisations at change to 8 and 12 weeks or for a child < 1 year receiving their vaccines later than the routine scheduled appointments.

Guidance on the use of prophylactic infant paracetamol suspension with Bexsero® vaccine

Given that fever has been a very common adverse reaction in trials, and in light of concerns raised that an increase in fever may have a detrimental impact on the uptake of future immunisations, the JCVI recommended the use of prophylactic paracetamol at the time of immunisation with Bexsero®. The JCVI agreed that parents and healthcare professionals needed to be informed and educated about the change in advice regarding the use of prophylactic paracetamol and the reactogenicity of Bexsero® when administered concomitantly with other routine childhood immunisations to reduce anxiety and concerns.

This is a change to previous advice whereby the prophylactic use of antipyretics was not routinely recommended as there was some evidence that antipyretics lowered the immune response to some of the routine infant vaccinations. Additionally, it was also felt that a low grade fever was to be expected following immunisation and such a response was an indication that the vaccine was triggering the appropriate immunological response. The latter remains true. However, the incidence of fever greater than 38°C when Bexsero® is administered at the same time as other childhood vaccines is greatly increased. Additionally, a recent study showed that giving a dose of paracetamol around the time of vaccination followed by a further two doses at 6-8 hourly intervals, significantly reduced the rates of fever associated with vaccination without affecting the immunogenicity of Bexsero® or other routine infant vaccines. Therefore, parents should be advised to give 2.5ml of infant paracetamol suspension (120mg/5ml) to their babies at the time of immunisation or as soon as possible after the vaccines are administered. Parents will also be advised to give two further doses at four to six hourly intervals. (See Table)

Table: Dosage and timing of infant paracetamol suspension (120mg/5ml) for the routine immunisation programme at 8 and 12 weeks [note 1]

Age of baby	Dose 1	Dose 2	Dose 3
2 months/ 8 weeks	One 2.5ml at the time of or as soon as possible after vaccination	One 2.5ml 4-6 hours after 1st dose	One 2.5ml 4-6 hours after 2nd dose
3 months/ 12 weeks	One 2.5ml at the time of or as soon as possible after vaccination	One 2.5ml 4-6 hours after 1st dose	One 2.5ml 4-6 hours after 2nd dose

Note 1: For premature babies, the dose should be calculated according to the infant's weight around the time of vaccination.
Note 2: Parents should also be advised not to give paracetamol to their child before vaccination in case it masks an illness that would mean the child's vaccinations should be delayed.

Healthcare professionals should ensure parents have access to the *Immunisation for babies up to one year old* vaccine leaflet before their 8 week primary vaccination appointment, for example when the parents register their baby at the practice or when they attend the 6-8 week check. This will alert parents to the need to buy liquid paracetamol in preparation for the 8 week immunisation appointment. Most local pharmacies, supermarkets and many local stores stock liquid paracetamol suspension.

There is also a factsheet for parents on giving infant paracetamol after the MenB vaccination. https://www.publichealth.hscni.net/publications/advice-giving-infant-paracetamol-after-menb-vaccination

What should health professionals advise parents regarding the discrepancy between the paracetamol packaging and patient information leaflet (PIL) advising a maximum of two doses of paracetamol post immunisations for infants aged 8 weeks? (Note: older packaging may still contain this advice)

The Commission on Human Medicines (CHM) has been consulted regarding the licencing restriction on Pharmacy (P) and General Sales List (GSL) paracetamol products which advise consulting a GP or pharmacist if more than two doses are required for an eight week old infant post-immunisation. The reason for this licensing is to ensure early diagnosis of systemic bacterial infection. The CHM supported the PHE recommendations for three doses of paracetamol post-immunisation with MenB and supported use of paracetamol for up to 48 hours post immunisations if required to manage post-immunisation fever in two month olds. This recommendation is based on the likelihood that fever is due to immunisation, this recommendation does not extend to fever at any other time and if the infant is otherwise unwell parents should trust their instincts and not delay seeking medical attention for the infant. Most infant paracetamol suspension manufacturers have updated their PILs since this consultation.

Parents can therefore be reassured that it is appropriate to follow PHA post-immunisation paracetamol dosing recommendations.

Healthcare professionals are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book chapters may differ from those in the Summary of Product Characteristics (SPC) for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and should be followed.

Does liquid paracetamol need to be administered when children receive their 12 months dose of Bexsero® when turning 1 year old?

In clinical vaccine trials, the most common adverse reaction observed in infants and children under two years of age was a high rate of fever (>38°C) when Bexsero® was administered at the same time as other routine childhood vaccines. As a result, the JCVI recommended the use of prophylactic liquid paracetamol when infants receive Bexsero® at the same time as other routine childhood vaccines such as DTaP/IPV/Hib and hep B at 8, 12 and 16 weeks of age. As these vaccines are not administered as part of the 12 month vaccines, there is no additional requirement to offer liquid paracetamol at that time. Furthermore, the infants are older and rates of fever are similar with and without Bexsero® administration at this age.

Can ibuprofen be offered as an alternative to paracetamol to reduce post-vaccination fever after Bexsero® is administered with other routine vaccines?

In a head-to-head clinical trial of paracetamol versus ibuprofen to reduce post-vaccination fever, ibuprofen (two or three doses) did not reduce the rate or intensity of post-vaccination fever compared to the control arm where infants did not receive any anti-pyretic. This finding needs to be validated in further studies but this does suggest that paracetamol should be the only recommended anti-pyretic to reduce post-vaccination fever in infants. Ibuprofen should, therefore, not be recommended as an alternative to paracetamol in this instance.

Should parents be worried about fever after vaccination?

Fever after vaccination with or without Bexsero® is common and nearly always under 39°C. Fever is a normal and expected response of the immune system against the vaccine antigens and generally

not harmful, but parents are often concerned about the risk of febrile convulsions or "fever fits". Typically, febrile convulsions occur from six months to five years of age and are very uncommon in younger age groups. In clinical trials involving several thousand infants receiving their routine vaccinations (including Bexsero®), febrile convulsions are very rarely reported. In one of the largest Bexsero® trials, where 1885 infants were recruited and vaccinated at four different visits without paracetamol prophylaxis, only one infant developed a febrile convulsion two days after receiving Bexsero®. In the subsequent study of 364 infants receiving Bexsero® with or without paracetamol , there wasn't a single case of febrile convulsion after any of the four vaccination visits.

What if a baby still has a fever after having had the three doses of paracetamol?

Some babies may still develop fever after vaccination, even after taking paracetamol. If a baby still has a fever after the first three doses of paracetamol but is otherwise well, you can continue giving the baby paracetamol. At least four hours should be left between doses and no more than four doses a day should ever be given in a 24 hour period. The child should be kept cool by making sure that they don't have too many layers of clothes or blankets on, and by giving them plenty of fluids. If parents/carers are concerned about their baby at any time, then they should trust their instincts and speak to their GP or call out-of-hours. Paracetamol is recommended for the prevention and treatment of fever after immunisation as there is evidence that it is safe and effective. If their baby still has a fever 48 hours after vaccination, they should speak to their GP or out-of-hours for advice.

What happens if the infant spits out the paracetamol suspension?

If the infant spits out or regurgitates at least half of the paracetamol suspension, then an additional dose (one dose of 2.5ml spoonful) of liquid paracetamol should be administered. If the second dose is spat out, do not give a third dose.

Does liquid paracetamol affect the immune response to the oral rotavirus vaccine?

Ideally the rotavirus vaccine and paracetamol should be given with a short interval between them, but the live vaccine virus should not be affected by close sequential administration of paracetamol syrup. A small volume of paracetamol is unlikely to add significantly to the volume or nature of the fluid present in the gut and therefore should not prevent the vaccine virus replicating to levels that provide a stimulus to the immune system. However, leaving a short interval between the vaccine and the paracetamol syrup may reduce the chance of the rotavirus vaccine being vomited back up.

Vaccine preparation and administration

How is Bexsero® administered and where is it administered?

The Bexsero® vaccine comes in a box that contains a prefilled syringe with a volume of 0.5mls. During storage, the contents of the syringe may settle with off-white deposits being noticeable. Before use, the pre-filled syringe must be shaken well so that any observable deposits are thoroughly mixed into the liquid forming a homogenous suspension that should be administered immediately. The vaccine should not be administered where there are variations in physical appearance (ie not a homogenous suspension) or signs of foreign particulate are observed after shaking.

When Bexsero® was introduced to the national vaccination programme, it was recommended that the vaccine be administered via intramuscular injection into the anterolateral aspect of the left thigh, ideally on its own, so that any local reactions could be monitored more accurately. Now that the vaccine has been in use for a number of years,

this is no longer necessary and either thigh can be used.

If for any reason it is necessary to administer another vaccine in the same limb, then a space of 2.5cms should be left between vaccine sites. The sites of administration of each vaccine should be noted in the individual's health records. Children with a bleeding disorder can have the vaccine administered by sub-cutaneous injection and the regional PGD can be used for this purpose (see chapter 4 the Green Book).

Healthcare professionals are reminded that some infants may receive additional vaccines as part of a selective immunisation programme around 12 months of age. Healthcare professionals are reminded that vaccines should not be administered into the same limb as the BCG vaccine for a period of 3 months from administration. Healthcare professionals are encouraged to discuss any recent immunisations at the 12 month appointment with parents.

Does Bexsero® contain latex?

The tip cap of the syringe may contain natural rubber latex. Although the risk for developing allergic reactions is very small, healthcare professionals should consider the benefit-risk prior to administering this vaccine to subjects with known history of hypersensitivity to latex. Further advice about administering vaccines to patients with a latex allergy can be found in chapter 6 of the Green Book. For a full list of excipients, healthcare professionals should read the manufacturer's Summary of Products Characteristics (SPCm).

Does Bexsero® contain any preservatives such as thiomersal?

No, Bexsero® does not contain thiomersal. For a full list of excipients, healthcare professionals should read the manufacturer's Summary of Products Characteristics (SPCm).

Does Bexsero® contain any porcine gelatin?

No, Bexsero® does not contain porcine gelatin. For a full list of excipients, healthcare professionals should read the manufacturer's Summary of Products Characteristics (SPCm).

Should Bexsero® be administered separately to other vaccines?

Bexsero® can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme, including pneumococcal, measles, mumps and rubella (MMR), diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. For rotavirus see page 6.

What should I do if a parent is concerned about the number of vaccines being administered to their child in one session?

It is understandable that some parents may become concerned about the number of vaccines being administered in one session, particularly at 12 months of age when three vaccines are scheduled to be administered. While these concerns are understandable, parents should be reassured by confident and knowledgeable healthcare professionals that the aim of immunisation is to provide protection against harmful diseases at the very earliest opportunity. Studies have demonstrated that there are no harmful effects from administering multiple vaccines in one session and there is no evidence to support arguments of overloading the immune system. From the moment a child is born, they are continually being exposed to a huge number of bacteria and viruses on a daily basis that the immune system is able to cope with and as a result becomes stronger (CDC). Additionally, administering multiple vaccines in one session is a routine occurrence in most countries around the world with no evidence of harmful effects.

What should I do if a parent requests MenB vaccine to be administered separately to the other routine primary immunisations?

Parents should be discouraged from delaying immunisation as this inevitably delays protection. The immunisation schedule has been designed to ensure optimal protection against diseases that are most common in the very young such as whooping cough, pneumococcal, Hib and meningococcal

disease. These diseases can be life-threatening and it is important for children to receive protection at the earliest possible opportunity.

How should I manage missed doses of Bexsero® vaccine?

MenB vaccination is offered to children up to their second birthday. Infants who have missed scheduled doses of MenB, or who have not received the recommended number of doses for their age, should be offered the vaccine at the earliest opportunity. These infants should be managed according to the https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status algorithm to ensure they are up to date with all immunisations.

- Infants younger than 12 months should receive 2 doses of MenB vaccine, 4 weeks apart. These infants should then follow the routine schedule and receive a booster dose in their second year of life. The booster dose is recommended to be given around the time of the first birthday but if primary doses have been given late (within 4 weeks of the first birthday), a minimum 4 week interval between primary and booster doses should be observed.

- Children aged one year to less than 2 years who have never had Men B vaccine should receive 2 doses of MenB vaccine with a 4 week interval between doses.

- Children aged one year to less than 2 years who only received 1 dose of MenB vaccine in their first year of life should receive 2 doses of MenB vaccine in their second year of life, with a 4 week interval between doses..

Can Bexsero® be administered at the same time as MenACWY vaccines?

Two studies assessing protein-based meningococcal B vaccines given with the MenACWY vaccines reported similar vaccine responses with no significant adverse events. Therefore, currently available evidence indicates that Bexsero® can be safely co-administered with MenACWY conjugate vaccines and other conjugate vaccines without affecting the immune response to other vaccines.

The manufacturer's Summary of Product Characteristics (SPCm) states that infants under six months of age should receive three doses of Bexsero® with a minimum of one month interval in addition to the booster dose at 12 months of age.

Why is Bexsero® only being recommended as a two dose schedule in infants aged under 6 months?

Although the Summary of Product Characteristics for Bexsero® states that three doses should be given in those less than one year of age, the JCVI have advised that provision of the 2+1 schedule would likely be sufficient to provide substantial protection against meningococcal B in infants and toddlers.

Healthcare professionals are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book may differ from those in the Summary of Product Characteristics for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and this advice should be followed.

What should I do if MenB vaccine was not administered at the 12 week appointment?

The reason for amending the schedule to administer the MenB vaccine at 12 weeks is to provide earlier protection against IMD.

If pneumococcal polysaccharide conjugate vaccine (PCV13) has been administered in error at the 12 week appointment, instead of MenB, and the child is still in the GP surgery, a dose of MenB vaccine should be offered immediately as MenB vaccine can be given at the same time as PCV13 vaccine where necessary.

If the child has left the surgery before the error is realised, the vaccinator should ensure that the

child is offered their second dose of MenB at their 16-week appointment.

A dose of (PCV13) administered in error at the 12 week appointment does not need repeating at the 16-week appointment. The move to administering PCV13 at 16 weeks is to accommodate the earlier administration of Bexsero at 12 weeks. Administering a dose of PCV13 in error at 12 weeks will not compromise pneumococcal protection and therefore a dose of PCV13 given from the age of 12 weeks would be classed as a valid dose.

What should I do if a child receives MenB vaccine at 16 weeks in error having already received it at 8 and 12 weeks?

Although studies have shown that infants make a good response to 2 doses of MenB vaccine, one of the licensed schedules for the Bexsero MenB vaccine is for three doses given 1 month apart. This means that the vaccine has been trialled this way and receiving 3 doses is not harmful. It is important to check that the MenB vaccine was not given instead of the PCV13 vaccine. If the PCV13 vaccine has not been given, it should be given as soon as possible after the error is realised.

What should I do if an infant who is not eligible inadvertently receives Bexsero®?

Infants older than 2 years of age are not recommended to receive Bexsero® and should not be offered additional meningococcal B vaccinations. Healthcare professionals should reassure parents that no further action is required and should report the administration error via their local governance system(s) so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

What should I do if the second dose of MenB vaccine was given less than 4 weeks after the first dose?

Provided that there is a minimum interval of 3 weeks (21 days) between the two doses of MenB vaccine, the second dose does not need to be repeated. If the second dose is administered at a shorter interval than 3 weeks, it should be discounted and an additional dose should be administered at least 4 weeks after the inadvertent dose was given (it may be given at the routine third immunisation visit at 16 weeks of age). As MenB vaccine was originally trialled and licensed as a 3-dose schedule given at least one month apart in infancy, an additional dose is acceptable and would not be expected to produce side effects beyond what may be seen following the first or second dose.

This information is intended to be used in exceptional circumstances, such as an inadvertent administration error. Deviation from the routine schedule should not be encouraged.

What should I do if the vaccine was administered at less than the recommended dose?

In the event that Bexsero® is administered at less than the recommended dose, vaccination will need to be repeated because the dose that the infant received may not be sufficient to evoke a full immune response. Where possible, the dose of Bexsero® should be repeated on the same day or as soon as possible after. In the event that the additional dose of Bexsero® cannot be administered at the same visit or day, arrangements should be made to administer the additional dose as soon as possible, thus not to delay future protection.

As Bexsero® has been associated with an increase in rates of fever when administered concomitantly with other childhood vaccines; prophylactic paracetamol should be offered with this Bexsero® dose.

Can Bexsero® be administered earlier than 8 weeks (2 months) to eligible infants travelling abroad?

The immunisation schedule has been designed to provide early protection against infections that are most dangerous for the very young. Recommendations for the age at which vaccines should be administered are informed by the age-specific risk for a disease, the risk of complications

and the ability to respond to the vaccine. Therefore, vaccines should be administered as closely to the schedule as possible.

Bexsero should not be routinely administered earlier than 8 weeks of age. However, in certain circumstances, the first set of primary immunisations (including MenB) can be administered from 6 weeks of age. For example, for infants who are due to travel to another country before they reach 8 weeks of age, when the primary immunisations are usually given. However, Bexsero® is licensed for use from the age of 8 weeks so if it is administered earlier than this, it should be treated as an 'off-label' use of a licensed vaccine and will require a PSD for its supply and administration.

If Bexsero® is inadvertently given prior to 8 weeks of age but the infant is over 6 weeks of age, this should count as a valid dose and does not need to be repeated. Doses given before 6 weeks of age should be discounted and the scheduled infant doses should still be given at 8 and 12 weeks of age.

Useful links

Meningococcal B Vaccination

- Bexsero® ▼ Summary of Product Characteristics, Novartis Vaccines. Updated 11 October 2016 www.medicines.org.uk/emc/product/5168/smpc
- Meningitis chapter of the Green Book https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22
- Meningococcal B (MenB) vaccination programme. Clarification re prescribing Men B vaccine. HSS(MD)9/2015 :Department of Health (NI) issued July 2016. https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-9-2015.pdf
- Vaccination of individuals with uncertain or incomplete immunisation status, algorithm from UK Health Security Agency (UKHSA). Updated 9 July 2025 https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status/
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General

- Joint Committee on Vaccination and Immunisation.

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Public Health Agency
12-22 Linenhall Street, Belfast BT2 8BS.
Tel: 0300 555 0114 (local rate).
www.publichealth.hscni.net

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