

PATIENT INFORMATION FOR MENINGOCOCCAL GROUP B VACCINE (BEXSERO)

Data as per HSE National Immunisation Office <http://www.hse.ie/eng/health/immunisation/>

What is Bexsero vaccine?

Bexsero is a meningococcal Group B (Men B) vaccine which protects against the majority of circulating Men B Strains.

Meningococcal Group B (Men B) is the bacteria which is the leading cause of meningitis and septicaemia in Ireland. There is an average of 170 cases of Men B in Ireland per year.

What age group can Bexsero be given to?

Bexsero is indicated for individuals from 2 months and older. There is no upper age limit. The minimum age at which Bexsero can be given is 8 weeks.

What is the vaccine dose and site?

The vaccine dose is 0.5ml and it is given into either the mid/upper thigh or the upper arm, depending on the persons age.

What is the schedule?

The schedule ranges from 2-3 doses as the primary course with a possible booster depending on the age. See schedule table below:

Age group	Primary Immunisation	Minimum Interval	Booster
2 - <6 months	Two doses	1 month	1 dose at 12 months of age
6 - <12 months	Two doses	2 months	1 dose over 12 months of age at least 2 months after the primary series
12 - <24 months	Two doses	2 months	1 dose 12 to 23 months after the primary series
2 - <11 years	Two doses	2 months	
11 years and older	Two doses	1 month	

Can other vaccines be given at or around the same time?

MenB vaccine can be given at the same as DTaP, IPV, Hib, Hep B, PCV, MenACWY, MMR and Varicella vaccines. Men B vaccine should be given in a different limb. However, to reduce adverse events of fever, local reactions, change in eating habits and irritability the National Immunisation Advisory Committee has recommended that **Bexsero MenB Vaccine should be administered with an interval of 1 week before or after Men C vaccine.**

Are there any reasons not to give the vaccine?

Contraindications

- Known hypersensitivity to any of the vaccine constituents including kanamycin and Latex.

Precautions

- Acute severe febrile illness; defer until recovery.
- Bexsero should be administered with caution to individuals with coagulation defects. If vaccines are given intramuscularly to those with a bleeding disorder or receiving anticoagulant treatment it is prudent to apply pressure to the vaccine site for 1-2 minutes after the injections. In those with a severe bleeding tendency vaccination can be scheduled shortly after administration of clotting factor replacement or similar therapy.
- Pregnancy: NIAC has stated that the potential risk of vaccination in pregnancy is unknown. Vaccination should be considered where there is a risk of exposure to meningococcal infection.

What are the side effects?

Bexsero was licensed in Europe (January 2013), Australia (August 2013) and Canada (December 2013).

More than half a million doses of Bexsero have been distributed worldwide and the side effect profile is as follows:

Infants and children up to 10 years

Very common (1/10):

Fever ($\geq 38^{\circ}\text{C}$) tenderness or pain at the injection site, skin rash, sleepiness, irritability, unusual crying, vomiting, diarrhoea, eating disorders

Uncommon (1/1000, <1/100):

High fever ($\geq 40^{\circ}\text{C}$), seizures (including febrile seizures), eczema

Rare (1/10,000, <1/1000):

Kawasaki disease, urticaria

From 11 years and older

Very common (1/10):

Tenderness or pain at the injection site, headache, nausea, myalgia, arthralgia

For more details see the Summary of Product Characteristics (on websites overleaf)

All adverse events should be reported to the Health Products Regulatory Authority (HPRA).

Should anti pyretics be given to reduce the risk of fever?

Yes. Paracetamol has been shown to reduce the incidence and severity of fever in children **under 2 years of age** and should be given at the time of or closely after vaccination in this age group.

Note: The studies were only conducted using paracetamol and not ibuprofen.

How long does it take for immunity to develop?

It takes about 2 weeks for immunity to develop but this wanes over time so subsequent doses are needed to maintain this immunity.

Can Bexsero be administered during pregnancy?

The potential risk of vaccination in pregnancy is unknown. Vaccination should be considered where there is a risk of exposure to meningococcal infection.