

MENINGOCOCCAL GROUP B VACCINE (BEXSERO)

Information for Health Professionals

What is Bexsero vaccine?

Bexsero is a meningococcal Group B (MenB) vaccine which is indicated for the active immunisation of individuals against invasive meningococcal disease caused by *Neisseria meningitidis* group B. The vaccine is manufactured using recombinant DNA technology and includes four antigenic proteins to protect against the majority of circulating MenB strains. Bexsero is not a live vaccine.

What are the constituents of Bexsero?

Four proteins

- NHBA (Neisseria Heparin Binding antigen)
- NadA (Neisserial adhesion A)
- fHbp (factor H binding protein)
- PorA

Adsorbed on aluminium hydroxide

Other constituents

- Sodium chloride
- Histidine
- Sucrose
- Water for injection
- The tip cap of the syringe may contain natural rubber latex.
- Kanamycin is used in early manufacturing process and is removed during the later stages of manufacture.

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.

Who should be given Bexsero?

Bexsero should be given to cases and all previously unimmunised close contacts of a case of any age and to control outbreaks of meningococcal disease as agreed by the Department of Public Health and the Health Protection Surveillance Centre.

What is the vaccine dose and site?

The vaccine dose is 0.5ml and the intramuscular site determined by the age

Patient's age	Intramuscular Site
Birth to <12 months*	Vastus lateralis muscle in anterolateral aspect of mid-or upper thigh
12 to <36 months	Vastus lateralis or deltoid muscle
3 years and older**	Densest portion of deltoid muscle – between acromion and muscle insertion

* Use a 16 mm needle in infants under 2.5-3 kg.

**Use a 40mm needle in females >90 kg, males >118 kg.

What does Bexsero look like?

Bexsero is presented as a single dose pre-filled 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 under 2.5-3kg (see above).

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.

What is the schedule?

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

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	
≥2 years	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, MenC, MenACWY, MMR and Varicella vaccines.

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)

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.

Can Bexsero be given to breastfeeding mothers?

Yes. Bexsero vaccine can be given to breastfeeding mothers.

Does Bexsero contain thiomersal?

No. There is no thiomersal in Bexsero.

Where to look for further information

- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Chapter 13 Meningococcal infection
<http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter13.pdf>
- Medicines information online Bexsero Summary of Product Characteristics
<http://www.medicines.ie/medicine/15903/SPC/Bexsero+Meningococcal+Group+B+vaccine+suspension+for+injection+in+pre-filled+syringe/>
- Centers for Disease Control (2014). Serogroup B Meningococcal Vaccine & Outbreaks
<http://www.cdc.gov/meningococcal/outbreaks/vaccine-serogroupb.html>