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Bexsero (*meningococcal group B vaccine [rDNA, component, adsorbed]*)

An overview of Bexsero and why it is authorised in the EU

What is Bexsero and what is it used for?

Bexsero is a vaccine used to protect individuals from the age of two months against invasive meningococcal disease caused by one group of the bacterium *Neisseria meningitidis* (group B). Invasive disease occurs when the bacteria spread through the body causing serious infections such as meningitis (infection of the membranes that surround the brain and spine) and septicaemia (blood infection).

Bexsero contains parts of the bacteria *N. meningitidis* group B.

How is Bexsero used?

Bexsero is available as a suspension for injection in a pre-filled syringe and can only be obtained with a prescription. It is given by deep injection into a muscle, preferably into the shoulder muscle, or into the thigh muscle in children under two years old. The number of injections given, and the interval between them, varies depending on the age of the patient.

Bexsero should be used according to official recommendations. For more information about using Bexsero, see the package leaflet or contact your doctor or pharmacist.

How does Bexsero work?

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When a person is given the vaccine, the immune system recognises the parts of the bacterium contained in the vaccine as 'foreign' and makes antibodies against them. When the person is then exposed to the bacterium, these antibodies together with other components of the immune system will be able to kill the bacteria and help protect against the disease.

Bexsero contains four proteins which are found on the surfaces of cells of the *N. meningitidis* group B bacterium. The vaccine is 'adsorbed'. This means that the proteins are fixed onto a compound containing aluminium, to stimulate a better immune response.



What benefits of Bexsero have been shown in studies?

Two main studies showed that Bexsero was effective at stimulating an immune response to *N. meningitidis* group B. The studies measured the production of protective antibodies which are able to kill the bacteria.

The first main study involved 2,627 children who were two months old when the study started. The effects of giving three doses of Bexsero at two-month intervals together with other routine infant vaccinations were compared with giving the routine vaccinations alone. This study was extended to look at the effects of giving a booster dose of Bexsero at or after 12 months of age to children who had already received Bexsero in early infancy, compared with giving two 'catch-up' doses to those who had not. The study showed that Bexsero was effective at stimulating an immune response to *N. meningitidis* group B. In addition, a single booster dose of Bexsero at 12 months of age produced a stronger immune response in children who had already received Bexsero than the first of two 'catch-up' doses in children of the same age who had not.

The second main study involved 1,631 adolescents aged between 11 and 17. The effects of giving one, two or three doses of Bexsero (at intervals of at least one month) were compared with giving placebo (a dummy treatment). The study showed that Bexsero was effective at stimulating an immune response to *N. meningitidis* group B and that two doses were needed to produce an adequate immune response.

A smaller supportive study was also carried out in adults and similar results were seen in this study.

What are the risks associated with Bexsero?

The most common side effects with Bexsero in children up to 10 years of age (seen in more than 1 patient in 10) are eating disorders, sleepiness, unusual crying, headache, diarrhoea, vomiting, rash, arthralgia (joint pain), fever and irritability as well as tenderness, swelling, hardness and redness of the skin at the injection site. The most common side effects with Bexsero in adolescents from 11 years of age and adults (seen in more than 1 patient in 10) are headache, nausea (feeling sick) and malaise (feeling unwell), myalgia (muscle pain) and arthralgia as well as pain, swelling, hardness and redness of the skin at the injection site.

For the full list of side effects and restrictions with Bexsero, see the package leaflet.

Why is Bexsero authorised in the EU?

The European Medicines Agency decided that Bexsero's benefits are greater than its risks and it can be authorised for use in the EU. Bexsero has been shown to produce a robust immune response to *N. meningitidis* group B and the risks are acceptable. Although group B meningococcal disease is relatively uncommon in Europe, it is more common in certain regions of Europe. Young children are most at risk, followed by adolescents.

What measures are being taken to ensure the safe and effective use of Bexsero?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Bexsero have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Bexsero are continuously monitored. Side effects reported with Bexsero are carefully evaluated and any necessary action taken to protect patients.

Other information about Bexsero

Bexsero received a marketing authorisation valid throughout the EU on 14 January 2013.

Further information on Bexsero can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports).

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