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EPAR summary for the public

Bexsero

meningococcal group B vaccine (rDNA, component, adsorbed)

This is a summary of the European public assessment report (EPAR) for Bexsero. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Bexsero.

What is Bexsero?

Bexsero is a vaccine which is available as a suspension for injection in a pre-filled syringe. It contains parts of the bacteria *Neisseria meningitidis* (*N. meningitidis*) group B.

What is Bexsero used for?

Bexsero is used to protect individuals from the age of two months against invasive meningococcal disease caused by one group of the bacterium *N. 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 should be used according to official recommendations.

The medicine can only be obtained with a prescription.

How is Bexsero used?

Bexsero is given by deep injection into a muscle, preferably into the shoulder muscle, or into the thigh muscle in children under two years old. In adults and adolescents aged 11 and over, two injections are given (at an interval of at least one month). In younger children, two injections are given (at an interval of at least two months), except in infants aged between two and five months who receive three injections (at intervals of at least one month). Children under two years old also receive an additional booster dose (at a time point determined by age).



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.

How has Bexsero been studied?

The ability of Bexsero to trigger the production of antibodies (immunogenicity) has been assessed in two main studies. 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 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). A smaller supportive study was also carried out in adults.

The studies assessed the ability of Bexsero to stimulate an immune response against *N. meningitidis* group B, by measuring the production of protective antibodies which are able to kill the bacteria.

What benefit has Bexsero shown during the studies?

The studies showed that Bexsero was effective at stimulating an immune response to *N. meningitidis* group B. The study in children also showed that 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 study in adolescents found that two doses were needed to produce an adequate immune response. Similar results were seen in adults.

What is the risk 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 all side effects and restrictions with Bexsero, see the package leaflet.

Why has Bexsero been approved?

The CHMP considered that Bexsero had been shown to produce a robust immune response to *N. meningitidis* group B and the risks were acceptable. Although group B meningococcal disease is relatively uncommon in Europe, the CHMP noted that it is more common in certain regions of Europe. The CHMP noted that young children are most at risk, followed by adolescents, and that there is no other vaccine authorised in the EU for meningitis caused by this group of the bacterium. Therefore, the CHMP decided that Bexsero's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Bexsero is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bexsero, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Bexsero

The European Commission granted a marketing authorisation valid throughout the European Union for Bexsero on 14 January 2013.

The full EPAR for Bexsero can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Bexsero, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2015.