Vaccine Essentials
Meningococcal group B vaccines

This document provides an overview of the two meningococcal B vaccines evaluated by the European Medicines Agency (EMA) to prevent invasive meningococcal disease (IMD) caused by *Neisseria meningitidis* group B. It also explains the scientific evidence supporting the vaccines' safety and effectiveness. It aims to support healthcare professionals' discussions with parents and carers.

About the disease

Invasive meningococcal disease (IMD) is a potentially life-threatening infection caused by the bacterium *Neisseria meningitidis*. It mostly affects young children, adolescents, and young adults. *N. meningitidis* subtypes B, C, W, and Y cause nearly all IMD in Europe.[1]

Data

In 2024, there were 2,263 reported cases of IMD (including 202 deaths) in the European Union/European Economic Area.[2]

IMD occurs when the bacteria spread through the body, causing serious infections[1,3]:

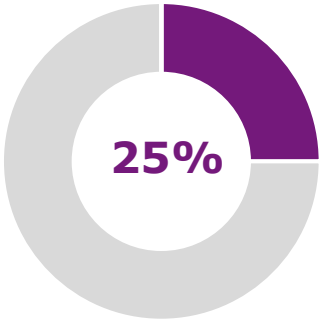
Meningitis

Inflammation of the membranes that surround the brain and spinal cord.

Septicaemia

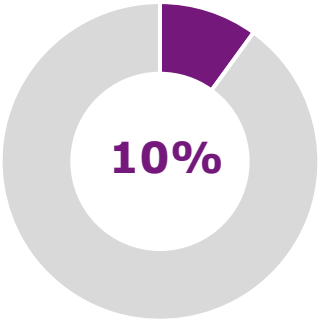
Poisoning of the blood.

Figure 1. Complications



Up to **one in four** infected people develop severe complications, such as loss of limbs, epilepsy and learning difficulties.[3-5]

Figure 2. Fatality rate



Around **one in ten** people with invasive meningococcal disease die.[1,3]

About the vaccines

Meningococcal vaccines help reduce the disease burden in young people, by protecting them against IMD and its serious health complications. MenACWY vaccines provide protection against subtypes A, C, W, and Y, but do not cover subtype B, which is responsible for over half of IMD cases in Europe.[1] This means that protection against subtype B also requires a meningococcal B (MenB) vaccine.

Meningococcal B vaccines approved in the EU via EMA

Name	**4CMenB** (Bexsero)	**MenB-fHBP** (Trumenba)
Target population	≥ 2 months	≥ 10 years
Mechanism of action	Bexsero and Trumenba contain parts of the bacteria *N. meningitidis* group B. The vaccines work by helping the body to make antibodies, which protect against IMD.	
Safety Bexsero PI Trumenba PI	For both vaccines, safety is well established. The most commonly observed adverse reactions at approval were injection site reactions (such as pain and swelling), fever, and fatigue. For the full list of possible side effects and their frequency, see the package leaflets within the Product Information (PI).	

How were the Meningococcal B vaccines approved?

MenB vaccines were approved after the scientific evaluation of their quality, safety and efficacy had demonstrated that their benefits outweighed their risks.

Before approval	**After approval**
Pre-approval studies showed the safety and the efficacy of MenB vaccines. The vaccines were found effective at stimulating a good immune response, based on measuring the production of antibodies which are able to kill MenB bacteria (immunogenicity).[6,7]	Post-approval studies complemented the initial evidence by providing additional data from a larger population that better reflects routine use in the real world.
Safety studies Both vaccines demonstrated a good safety profile. In children, it was comparable to other vaccines routinely administered in similar ages.	**Safety studies** With more than 3 million doses administered globally, no serious post-vaccination side effects were identified in routine use.[8]
Efficacy based on immunogenicity studies As invasive meningococcal disease is rare, conducting traditional efficacy trials was not feasible. Instead, regulators approved the vaccines based on successful immunogenicity studies.[6,7]	**Effectiveness studies** Studies were carried out to confirm the effectiveness of MenB vaccines in real-world conditions.

By supplementing the initial evidence (pre-approval) with additional data (post-approval), regulators were able to further confirm the vaccines' safety, effectiveness, as well as their favourable benefit/risk balance.

Effectiveness

Bexsero: In a study conducted among children in the UK, the vaccine showed a significant reduction (75%) in IMD cases.[9,10]

Trumenba: The vaccine was successfully used to control a local outbreak in people aged over 18 years in the US.[11]

EU paediatricians' perspective

The meningococcal B vaccines represent a success story on the prevention of a very serious disease mainly affecting infants and teenagers. In clinical practice, in a child with fever, if all meningococcal immunisation is up-to-date, the risk of severe illness including meningitis is really low.

Dr. Hans J. Dornbusch
Paediatrician, Chair of the Immunisation Strategic Advisory Group, European Academy of Paediatrics

References

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2. European Centre for Disease Prevention and Control. 18 March 2026. Very low risk for the EU/EEA from the outbreak of invasive meningococcal disease in Kent, England
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More information

European Vaccination Information Portal. Meningococcal disease

DARWIN EU® - Coverage of meningococcal vaccines in the target population in Europe | HMA-EMA Catalogues of real-world data sources and studies