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EPAR summary for the public

Trumenba

meningococcal group B vaccine (recombinant, adsorbed)

This is a summary of the European public assessment report (EPAR) for Trumenba. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Trumenba.

For practical information about using Trumenba, patients should read the package leaflet or contact their doctor or pharmacist.

What is Trumenba and what is it used for?

Trumenba is a vaccine used to protect individuals from 10 years old against invasive meningococcal disease caused by a group of bacteria called *Neisseria meningitidis* group B.

Invasive disease occurs when these bacteria spread through the body causing serious infections such as meningitis (infection of the membranes that surround the brain and spinal cord) and septicaemia (blood infection).

How is Trumenba used?

Trumenba can only be obtained with a prescription and should be used according to official recommendations. It is available in a pre-filled syringe and is given by injection into a muscle, preferably in the shoulder. Initial treatment may either involve 2 injections at least 6 months apart, or 2 injections at least 1 month apart followed by a third injection at least 4 months later. In patients at greater risk of invasive meningococcal disease, an additional booster dose may be considered later on.

How does Trumenba 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

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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.

Trumenba contains two components, proteins that are found in the outer coats of *Neisseria meningitidis* group B bacteria. These proteins are fixed onto a compound containing aluminium (adsorbed), which helps to stabilise them, allowing the immune system to respond to them.

What benefits of Trumenba have been shown in studies?

Trumenba has been shown to trigger the production of protective levels of antibodies against *Neisseria meningitidis* group B in two main studies. The first study involved around 3,600 participants aged 10 to 18 years, and the second study involved around 3,300 young adults between 18 and 25 years of age; none of the participants had previously been vaccinated against *N. meningitidis* group B. Those taking part were given 3 doses of the vaccine and antibody response against 4 main test strains of the bacteria (the ones usually responsible for disease in Europe) was measured one month after the last injection. The studies also looked at response to 10 other, secondary strains of *N. meningitidis* group B.

Antibodies were produced in sufficient quantities to provide protection against the 4 main test strains in between 80 and 90% of those in the first study, depending on the strain; 84% of those given the vaccine had protective antibodies against all 4 strains when tested. In the second study sufficient amounts of antibodies were produced in 79 to 90% of cases, and protective levels of antibodies against all 4 strains were seen in 85% of participants. Antibody responses were also seen against the 10 secondary strains and confirmed the responses seen with the 4 main strains.

Supportive studies were also carried out, which showed that 2 doses of the vaccine achieved a broadly similar antibody response to 3 doses, and that even though protective antibody levels declined over time they could be improved by an additional booster dose after both 2- and 3-dose treatments.

What are the risks associated with Trumenba?

The most common side effects with Trumenba (which may affect more than 1 in 10 people) are pain, redness or swelling at the site of the injection, headache, tiredness, chills, diarrhoea, nausea (feeling sick), and muscle or joint pain.

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

Why is Trumenba approved?

The available data indicated that Trumenba should provide broad protection against the strains of *Neisseria meningitidis* group B that are currently found in Europe, whether given in a 3-dose or a 2-dose schedule. As the protection provided seemed to decline over time, a booster dose should be considered in recipients who were thought to be at continued risk of invasive meningococcal disease. Although side effects were common, they appeared to be within acceptable limits. Further planned or ongoing studies are expected to provide more information on Trumenba's effectiveness.

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that based on available data Trumenba's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about Trumenba

The European Commission granted a marketing authorisation valid throughout the European Union for Trumenba on 24 May 2017.

The full EPAR for Trumenba 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 Trumenba, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2017.