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EPAR summary for the public

Menveo

meningococcal group A, C, W135 and Y conjugate vaccine

This document is a summary of the European Public Assessment Report (EPAR) for Menveo. 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 Menveo.

What is Menveo?

Menveo is a vaccine. It is available as a powder and solution that are mixed together to make a solution for injection. It contains parts of the bacterium *Neisseria meningitidis* (*N. meningitidis*).

What is Menveo used for?

Menveo is used to protect adults and children from the age of two against invasive disease caused by four groups of the bacterium *N. meningitidis* (A, C, W135, and Y).

Menveo is used in people who are at risk of exposure to the bacterium. 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).

The vaccine should be given according to official recommendations.

The vaccine can only be obtained with a prescription.

How is Menveo used?

Menveo is given as a single injection preferably into the shoulder muscle. Menveo must not be given into a blood vessel or into or under the skin.

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How does Menveo 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 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.

Menveo contains small amounts of oligosaccharides (a type of sugar) extracted from four groups of the *N. meningitidis* bacterium: A, C, W135 and Y. These have been purified, then 'conjugated' (attached) to a protein from the bacterium *Corynebacterium diphtheriae*. This helps to enhance the immune response.

How has Menveo been studied?

The ability of Menveo to trigger the production of antibodies (immunogenicity) was assessed in a main study involving almost 4,000 participants aged 11 years and above and in a second main study involving almost 3,000 children between two and 10 years old. Menveo was compared with a similar conjugated vaccine against *N. meningitidis*. The main measure of effectiveness was whether Menveo was as good as the comparator vaccine at stimulating immune response against the four types of *N. meningitidis* oligosaccharides.

What benefit has Menveo shown during the studies?

The results of the main studies showed that Menveo was as effective as the comparator vaccine in stimulating an immune response against all four types of *N. meningitidis* oligosaccharides in adults and children from the age of two. The number of people who had an immune response against the oligosaccharides was similar for the two vaccines.

What is the risk associated with Menveo?

The most common side effects with Menveo in adults and children from the age of 11 (seen in more than 1 patient in 10) are headache, nausea (feeling sick), malaise (feeling unwell), myalgia (muscle pain), as well as pain, erythema (reddening of the skin) and induration (hardening) at the site of injection. In children between two and 10 years old, the most common side effects were similar and also included sleepiness and irritability. For the full list of all side effects reported with Menveo, see the package leaflet.

Menveo must not be used in people who are hypersensitive (allergic) to the active substances or any of the other ingredients, including diphtheria toxoid. The vaccine must not be given to anyone who has had a life-threatening reaction to a vaccine that contains similar components in the past. Vaccination should be postponed in people who have a high fever.

Why has Menveo been approved?

The CHMP noted that five *N. meningitidis* bacterial groups (A, B, C, W135 and Y) are responsible for invasive disease, and that Menveo provides broader protection than other available vaccines. The Committee noted that Menveo offers the benefits of conjugated vaccines, including producing a stronger immune response in young children. The Committee therefore decided that Menveo's benefits are greater than its risks in people who are at risk of exposure to *N. meningitidis* bacterium, and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Menveo 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 Menveo, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Menveo

The European Commission granted a marketing authorisation valid throughout the European Union for Menveo on 15 March 2010.

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

This summary was last updated in 09-2015.