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Penbraya (*meningococcal groups A, C, W, Y conjugate and group B vaccine (recombinant, adsorbed)*)

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

What is Penbraya and what is it used for?

Penbraya is a vaccine used to protect people aged 10 years and older against severe meningococcal disease caused by types A, B, C, W and Y of the bacteria *Neisseria meningitidis*.

Meningococcal disease can lead to meningitis (inflammation of the membranes surrounding the brain and spinal cord) and septicaemia (blood poisoning).

Penbraya contains small amounts of molecules from *N. meningitidis* types A, B, C, W and Y.

How is Penbraya used?

Penbraya can only be obtained with a prescription and should be used according to official recommendations.

The vaccine is given as two injections 6 to 12 months apart, usually into the muscle of the upper arm. For people at high risk of severe meningococcal disease, an additional injection may be necessary.

For more information about using Penbraya, see the package leaflet or contact your doctor or pharmacist.

How does Penbraya work?

Penbraya is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend the body against a specific disease.

Penbraya contains molecules from specific types of *N. meningitidis*. When a person is given the vaccine, the immune system recognises the molecules as foreign and makes antibodies against them. If the person later comes into contact with the bacteria, these antibodies, together with other components of the immune system, will be able to fight off the bacteria more effectively and so help protect the person against severe infections.

Some of the molecules from *N. meningitidis* in Penbraya are fixed (adsorbed) onto a compound containing aluminium, which helps stabilise them, allowing the immune system to respond to them.

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What benefits of Penbraya have been shown in studies?

A main study involving around 2,400 people from 10 to 25 years of age compared Penbraya with two vaccines already used to protect against infection by *N. meningitidis:* Trumenba, which targets type B, and Menveo, which targets types A, C, W and Y.

In this study, the proportion of people who had levels of antibodies that can be considered protective against type B after vaccination with Penbraya was similar to that seen after vaccination with Trumenba. In addition, the proportion of people who had levels of antibodies that can be considered protective against types A, C, W and Y after vaccination with Penbraya was similar to that seen after vaccination with Menveo.

Based on these results, Penbraya is expected to offer protection against severe meningococcal disease caused by the 5 types of *N. meningitidis*.

What are the risks associated with Penbraya?

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

The most common side effects with Penbraya (which may affect more than 1 in 10 people) include pain, swelling and redness at the injection site, tiredness, headache and muscle pain.

Penbraya must not be used in people allergic to the active substance or any of the other ingredients in the vaccine.

Why is Penbraya authorised in the EU?

Penbraya triggers an immune response against *N. meningitidis* A, B, C, W and Y in adults and children from 10 years of age. This immune response is expected to protect against disease caused by these bacteria. At the time of approval, two separate vaccines were necessary to protect against *N. meningitidis* types A, B, C, W and Y. Penbraya, which targets all five types in a single vaccine, may help simplify vaccination programmes. Regarding safety, the vaccine's side effects are mostly mild to moderate.

The European Medicines Agency therefore decided that Penbraya's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Penbraya

Penbraya received a marketing authorisation valid throughout the EU on 14 November 2024.

Further information on Penbraya can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/penbraya.

This overview was last updated in 11-2024.