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Dengvaxia (*dengue tetravalent vaccine* [*live, attenuated*])

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

What is Dengvaxia and what is it used for?

Dengvaxia is a vaccine used to help protect against dengue disease in people aged 6 to 45 years who have had a previous dengue virus infection.

Dengue disease is a mosquito-borne tropical disease caused by the dengue virus, leading to mild, flu-like symptoms in most people. However, a small number of patients develop severe disease, with potentially fatal bleeding and organ damage. The risk of severe disease is higher in people who have been infected a second time.

There are several varieties (called serotypes) of dengue virus and Dengvaxia protects against serotypes 1, 2, 3 and 4.

Dengvaxia contains attenuated (weakened) yellow fever viruses that have been modified so that they contain proteins from dengue virus.

How is Dengvaxia used?

Dengvaxia must only be given to people who have had a positive test result showing a previous infection with dengue virus. The vaccine is given as three doses, six months apart. The injection is given under the skin, preferably in the upper arm.

Dengvaxia can only be obtained with a prescription and should be used according to official recommendations. For more information about using Dengvaxia, see the package leaflet or contact your doctor or pharmacist.

How does Dengvaxia work?

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend the body against a disease. Dengvaxia contains weakened viruses that do not cause disease. When a person is given the vaccine, the immune system recognises the dengue proteins in the weakened viruses as 'foreign' and makes antibodies against them. In the future, when the person comes into contact with

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dengue virus, these antibodies together with other components of the immune system will be able to kill the virus and help protect against the disease.

What benefits of Dengvaxia have been shown in studies?

Three studies were carried out in Asia and Latin America involving over 35,000 children aged 2 to 16 years. The studies included both children who had and had not been infected with dengue virus in the past. Children were given either three injections of Dengvaxia or three injections of placebo (a dummy vaccine) with six months between each injection. Cases of dengue disease were recorded for one year, starting from four weeks after the last injection.

Overall, among children aged between 6 and 16 years and who had had previous dengue infection, there were close to 80% fewer cases of dengue disease in children vaccinated with three doses of Dengvaxia compared with those given placebo. This means that the vaccine had an efficacy of close to 80% in children who had dengue in the past. However, among children who had not had previous dengue infection, the risk of severe dengue disease if they later became infected with the virus was higher in those vaccinated than in those given placebo.

Additional studies suggest that the vaccine is also effective in people aged 16 to 45 years.

Available data are not sufficient to confirm how well the vaccine works and whether it is sufficiently safe in children younger than 6 years of age and previously infected by dengue virus.

What are the risks associated with Dengvaxia?

The most common side effects with Dengvaxia (which may affect more than 1 in 10 people) are headache, redness and pain at the injection site, feeling generally unwell, muscle pain, weakness and fever. Allergic reactions, which may be severe, are a very rare side effect of Dengvaxia.

Dengvaxia must not be given to people with weakened immune systems, including people whose immune system has been weakened by HIV infection or medicines such as cancer medicines or high doses of corticosteroids. Dengvaxia must also not be given to women who are pregnant or breastfeeding.

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

Why is Dengvaxia authorised in the EU?

Dengvaxia is effective at reducing the number of cases of dengue disease in people aged between 6 and 45 years who have had the infection in the past. However, people who have not had dengue infection in the past may have a higher risk of severe dengue disease if they become infected with the virus after vaccination with Dengvaxia. Therefore, the vaccine should only be given to people who have had a previous dengue infection, as confirmed by laboratory testing.

There is no other vaccine for dengue disease and neither is there a specific treatment. Dengvaxia's side effects are usually mild or moderate and do not last longer than three days.

The European Medicines Agency therefore decided that Dengvaxia's benefits are greater than its risks and it can be authorised for use in the EU in areas where dengue disease is endemic.

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

The company that markets Dengvaxia will provide educational material for healthcare professionals with information on the use of Dengvaxia including the need to test for previous dengue infection and how to detect early dengue disease.

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

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

Other information about Dengvaxia

Dengvaxia received a marketing authorisation valid throughout the EU on 12 December 2018.

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

This overview was last updated in 11-2021.