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SCIENCE MEDICINES HEALTH

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Dengue Tetravalent Vaccine (Live, Attenuated) Takeda (*dengue tetravalent vaccine [live, attenuated]*)

An overview of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda and why it received a positive opinion

What is Dengue Tetravalent Vaccine (Live, Attenuated) Takeda and what is it used for?

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda is a vaccine that helps protect against dengue disease. The vaccine can be given to adults, adolescents and children from 4 years of age.

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.

This vaccine contains attenuated (weakened) versions of dengue virus serotypes (varieties) 1, 2, 3 and 4.

This overview is for the vaccine intended for use outside the EU. An identical vaccine, Qdenga, is authorised in the European Union.

How is Dengue Tetravalent Vaccine (Live, Attenuated) Takeda used?

Arrangements for supply of this vaccine will be the responsibility of national medicines regulators.

The vaccine is given as an injection under the skin of the upper arm. The vaccination course consists of 2 injections given 3 months apart.

For more information about using Dengue Tetravalent Vaccine (Live, Attenuated) Takeda, see the package leaflet or contact your healthcare provider.

How does Dengue Tetravalent Vaccine (Live, Attenuated) Takeda work?

Dengue disease is caused by infection with dengue virus, which is transmitted to humans through the bite of mosquitos. This vaccine contains attenuated versions of the 4 virus serotypes. These versions cannot cause the disease, but they 'teach' the immune system (the body's natural defences) to defend the body against the virus.

When a person is given the vaccine, the immune system identifies the attenuated serotypes as foreign

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and makes antibodies against them. When a person is later exposed to the virus, the immune system recognises it and can quickly make many more antibodies, which then neutralise the virus before it can cause dengue disease.

What benefits of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda have been shown in studies?

This vaccine was shown to be effective at preventing fever due to dengue disease in children and adolescents in the 12 months following the second injection. In a main study in 8 countries in Latin America and the Asia Pacific region, about 20,000 children between the age of 4 to 16 years were given Dengue Tetravalent Vaccine (Live, Attenuated) Takeda or placebo (a dummy injection). The study showed a reduction by 80% in the number of fever cases caused by confirmed dengue disease in those who received the vaccine (61 cases in 12,700 children) compared with those given placebo (149 cases in 6,316 children).

The vaccine also reduced hospitalisation due to dengue by 90%. In the 18 months after receiving the second injection, 0.1% (13 out of 12,700) of children given the vaccine were hospitalised because of confirmed dengue, compared with 1.0% (66 out of 6,316) of children given placebo.

What are the risks associated with Dengue Tetravalent Vaccine (Live, Attenuated) Takeda?

The most common side effects with Dengue Tetravalent Vaccine (Live, Attenuated) Takeda (which may affect more than 1 in 5 people) are pain and redness at the injection site, headache, muscle pain, feeling generally unwell and weakness. Up to 1 in 10 people may experience fever. These side effects, which are usually of mild to moderate severity and resolve within a few days, are less frequent after the second dose of the vaccine than after the first.

This vaccine must not be used in people who had a hypersensitivity (allergic) reaction to a previous dose of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda. It must also not be used in individuals with a weakened immune system because of a disease, medicines that affect the immune system or HIV infection. The vaccine must not be used in women who are pregnant or breastfeeding.

For the full list of side effects and restrictions of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda, see the package leaflet.

Why did Dengue Tetravalent Vaccine (Live, Attenuated) Takeda receive a positive opinion?

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda provides protection against fever and hospitalisation resulting from dengue disease caused by any of the 4 dengue virus serotypes. Side effects are mostly mild to moderate in severity and disappear within a few days.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that the benefits of the vaccine outweigh its risks and issued a positive scientific opinion.

What measures are being taken to ensure the safe and effective use of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda are continuously monitored. Suspected side effects reported with Dengue Tetravalent Vaccine (Live, Attenuated) Takeda are carefully evaluated and any necessary action taken to protect patients.

Other information about Dengue Tetravalent Vaccine (Live, Attenuated) Takeda

The European Medicines Agency gave a positive opinion for Dengue Tetravalent Vaccine (Live, Attenuated) Takeda on 13 October 2022. The Agency assessed Dengue Tetravalent Vaccine (Live, Attenuated) Takeda as part of its cooperation with the World Health Organization, whereby the Agency evaluates medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

Further information on Dengue Tetravalent Vaccine (Live, Attenuated) Takeda can be found on the Agency's website: ema.europa.eu/en/opinion-medicine-use-outside-EU/human/dengue-tetravalent-vaccine-live-attenuated-takeda

This overview was last updated in 11-2022.