13 October 2022
EMA/CHMP/781055/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda

dengue tetravalent vaccine (live, attenuated)

On 13 October 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004[1] for the medicinal product Dengue Tetravalent Vaccine (Live, Attenuated) Takeda, intended for prophylaxis against dengue disease. This medicinal product has been developed by Takeda GmbH.

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda will be available as a powder and solvent for solution for injection. The active substance of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda is dengue tetravalent vaccine (live, attenuated), a viral vaccine (ATC code: J07BX04) containing live attenuated dengue viruses which replicate locally and elicit humoral and cellular immune responses against the four dengue virus serotypes.

The benefit of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda is the prevention of dengue fever, including lowering the risk of hospitalisation. The most common side effects are injection site pain, headache, myalgia and asthenia.

The full indication is:

> Dengue Tetravalent Vaccine (Live, Attenuated) Takeda is indicated for the prevention of dengue disease in individuals from 4 years of age.
>
> The use of Dengue Tetravalent Vaccine (Live, Attenuated) Takeda should be in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR).

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda is intended exclusively for markets outside the European Union.

[1] Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union