13 October 2022
EMA/CHMP/781052/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Qdenga

dengue tetravalent vaccine (live, attenuated)

On 13 October 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Qdenga, intended for prophylaxis against dengue disease. The applicant for this medicinal product is Takeda GmbH.

Qdenga will be available as a powder and solvent for solution for injection. The active substance of Qdenga 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 Qdenga 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:

> Qdenga is indicated for the prevention of dengue disease in individuals from 4 years of age.
>
> The use of Qdenga 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) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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