



dengue vaccine (DENGvAXIA°)

Not for large-scale use

Abstract

● Dengue is an infection caused by a virus with 4 known serotypes. The infection is often asymptomatic and generally self-limiting. When infected for a second time, a patient's risk of severe and potentially fatal dengue is increased. As of late 2019, dengue prevention is mainly based on control of the mosquitoes that transmit the virus in endemic areas (tropical or subtropical regions) and personal protection against mosquito bites.

● A vaccine containing live attenuated viruses expressing antigens of the 4 known dengue virus serotypes (Dengvaxia°, Sanofi Pasteur) has been granted marketing authorisation in the European Union. It is authorised for use in persons aged 9 years to 45 years who have previously been infected with the virus and live in an endemic area.

● The dengue vaccine has not been evaluated in persons living in non-endemic regions or in travellers visiting an endemic region. In three randomised placebo-controlled trials in about 35 000 children aged 2 to 16 years living in endemic areas, the vaccine was effective in reducing the incidence of symptomatic dengue, including severe forms, during the two years following the first injection. Its efficacy increased with age. Preliminary data from long-term follow-up suggest that its efficacy diminishes over time.

● An increased incidence of severe dengue was observed in vaccinated children aged 2 to 5 years, and in vaccinated children who had not previously been infected with one of the dengue viruses. Yet no test that is sufficiently simple to perform and has the required proven performance characteristics for routine identification of prior infection is available as of 2019.

● No trials have evaluated the effect of the vaccine on clinical outcome measures in adults aged 18 to 45 years.

● About half of the patients included in trials had an injection site reaction. The systemic adverse effects were those generally observed with vaccines: headache, fatigue, myalgia, malaise, and allergic reactions, including anaphylactic reactions.

● As the dengue vaccine is a live attenuated vaccine, pregnant women and immunocompromised patients are at risk of developing serious infection with the viruses contained in the vaccine.

NOTHING NEW

The dengue vaccine reduced the incidence of dengue, including severe forms, in children living in endemic areas. However, this vaccine is unsuitable for mass immunisation in endemic areas as of 2019, because it can increase the risk of severe dengue in persons not previously infected with dengue virus. Yet no test suitable for routine screening and proven to possess the required performance characteristics is available to identify these children. In practice, the only population in which the harm-benefit balance of this dengue vaccine appears favourable is children for whom there is documented evidence of positive serological testing at the time of a prior infection. Its efficacy appears to wane over time and the benefit of a booster dose has not been evaluated. As of 2019, the prevention of dengue relies above all on vector control in endemic areas, and personal protection against mosquito bites.

DENGvAXIA° - dengue vaccine powder and solvent for suspension for subcutaneous injection

■ dengue tetravalent vaccine

■ **Indication:** "prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in individuals 9 to 45 years of age with prior dengue virus infection and living in endemic areas". [EU centralised procedure]

■ **Dosage:** "3 injections of one reconstituted dose (0.5 ml) to be administered at 6-month intervals".

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