QDENGATM (Dengue Tetravalent Vaccine (live, attenuated))

IMPORTANT SAFETY INFORMATION

Administration: The use of Qdenga should be in accordance with official recommendations. The vaccine is given as a subcutaneous injection preferably in the upper arm in the region of deltoid. Qdenga must not be injected intravascularly, intradermally or intramuscularly. The vaccination course consists of 2 injections given 3 months apart.

Contraindications: This vaccine must not be used in

- people who had a hypersensitivity reaction to a previous dose of Qdenga. As with all
 injectable vaccines, appropriate medical treatment and supervision must always be readily
 available in the event of a rare anaphylactic reaction following administration of the vaccine
- individuals with weakened immune system because of a disease, medicines (such as chemotherapy or high doses of systemic corticosteroids) or HIV infection. Vaccination with Qdenga should be postponed in subjects suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in a deferral of vaccination.
- women who are pregnant or breastfeeding. As with other live attenuated vaccines, women
 of childbearing potential should avoid pregnancy for at least one month following
 vaccination

Adverse reactions: <u>Very common</u>: upper respiratory tract infection, decreased appetite, irritability, headache, somnolence, myalgia, injection site pain, injection site erythema, malaise, asthenia, fever. <u>Common</u>: nasopharyngitis, pharyngotonsillitis, arthralgia, injection site swelling, injection site bruising, injection site pruritus, influenza like illness. <u>Uncommon</u>: bronchitis, rhinitis, dizziness, diarrhoea, nausea, abdominal pain, vomiting, rash, pruritus, urticaria, injection site haemorrhage, fatigue, injection site discolouration.

It is recommended to continue personal protection measures against mosquito bites after vaccination. Individuals should seek medical care if they develop dengue symptoms or dengue warning signs

For detailed safety information, including full side effect profile and interactions, refer to the Qdenga SmPC.