ABBREVIATED PRESCRIBING INFORMATION

QDENGA™▼ (Dengue Tetravalent Vaccine [Live, Attenuated])

Please consult the Summary of Product Characteristics (SmPC) before prescribing.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See Section 4.8 of the SmPC for how to report adverse reactions.

Product Name: Qdenga powder and solvent for solution for injection. **Indication:** 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. **Presentation:** 1 dose contains: ≥ 3.3, ≥ 2.7, ≥ 4.0 and ≥ 4.5 log10 PFU live attenuated Dengue virus serotype 1, 2, 3 and 4, respectively. **Posology & Administration:** *Individuals from 4 years of age:* Qdenga should be administered as a 0.5 ml dose given subcutaneously at a two-dose (0 and 3 months) schedule. **Contraindications:** Hypersensitivity to the active substances or excipients listed, or to previous Qdenga dose. Individuals with congenital or acquired immune deficiency, including immunosuppressive therapies such as chemotherapy or high doses of systemic corticosteroids (eg, 20 mg/day or 2 mg/kg body weight/day of prednisone for 2 weeks or more) within 4 weeks prior to vaccination. Individuals with symptomatic HIV infection or asymptomatic HIV infection with impaired immune function. Pregnant and breast-feeding women. **Warnings & Precautions:** The name and the batch number of the administered product should be clearly recorded. Protective immune response may not be elicited in all vaccinees against all dengue serotypes and may decline over time. It is currently unknown whether a lack of protection could result in an increased severity of dengue. Continued personal protection measures against mosquito bites post-vaccination are recommended. Appropriate medical treatment and supervision must be readily available in case of rare anaphylactic reaction post-vaccination. Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting. Vaccination should be preceded by a review of the individual's medical history. Vaccination should be postponed in subjects suffering from acute severe febrile illness. Women of childbearing potential should avoid pregnancy for ≥1 month following vaccination. Qdenga must not be administered by intravascular, intradermal, or intramuscular injection. **Interactions:** Patients receiving treatment with immunoglobulins or blood products containing immunoglobulins are recommended to wait for ≥6 weeks, and preferably 3 months, following treatment before administering Qdenga. Qdenga should not be administered to subjects receiving immunosuppressive therapies within 4 weeks prior to vaccination. Qdenga may be administered concomitantly with a hepatitis A vaccine or a yellow fever vaccine. **Fertility, Pregnancy & Lactation:** No specific studies have been performed on fertility in humans. Qdenga is contraindicated during pregnancy and breast-feeding. **Adverse Reactions:** Most frequently reported reactions in subjects 4 to 60 years of age were injection site pain (50%), headache (35%), myalgia (31%), injection site erythema (27%), malaise (24%), asthenia (20%), and fever (11%). Very common: (≥1/10 of subjects): upper respiratory tract infection[a], decreased appetite[c], irritability[c], headache, somnolence[c], myalgia, injection site pain, injection site erythema, malaise, asthenia, fever. Common (≥1/100 to <1/10): nasopharyngitis, pharyngotonsillitis[b], injection site swelling, injection site bruising[e], injection site pruritus[e], influenza like illness. Uncommon (≥1/1,000 to <1/100): bronchitis, rhinitis, dizziness, diarrhoea, nausea, abdominal pain, vomiting, rash[d],

pruritus[e], urticaria, arthralgia, injection site haemorrhage[e], fatigue[e], injection site discolouration[e]. Very Rare (≥1/10,000 to <1/1,000): Angioedema. [a]Includes upper respiratory tract infection and viral upper respiratory tract infection. [b]Includes pharyngotonsillitis and tonsillitis. [c]Collected in children 4-6 years of age in clinical studies. [d]Includes rash, viral rash, rash maculopapular, and rash pruritic. [e]Reported in adults in clinical studies. **Refer to the SmPC for details on full side effect profile and interactions**. **Overdose**: No case of overdose has been reported. **Name and Address of Marketing Authorisation Holder**: Takeda GmbH, Byk-Gulden-Str. 2, 78467 Konstanz, Germany. Date of revision: June 2022.

Further information is available on request.
Suspected Adverse Reactions should be reported to the authorities in your country as required by local law. Adverse reactions should also be reported to Takeda at xxxx@takeda.com