Administration Guide:

Qdenga™▼ (Dengue tetravalent vaccine - live, attenuated)
Powder and solvent for solution for injection in pre-filled syringe
Qdenga™▼ this medicinal product is subject to additional monitoring
Prescribing information can be found on page 2
Created and produced by Takeda UK for Healthcare Professionals in Northern Ireland

Qdenga™ is a 2-component vaccine that consists of a vial containing lyophilised vaccine and solvent provided in the pre-filled syringe. The lyophilised vaccine must be reconstituted with the solvent prior to administration.[1]

Storage[1]:

- Store in a refrigerator (2°C to 8°C)
- Do not freeze
- After reconstitution with the solvent provided, Qdenga™ should be used immediately. If not immediately, Qdenga™ must be used within 2 hours
- Never use Qdenga™ after the expiration date stated on the carton

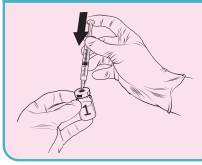
Contains:

- Vial containing lyophilised vaccine (powder)
- Pre-filled syringe containing solvent
- 2 needles

Reconstitution and administration[1]

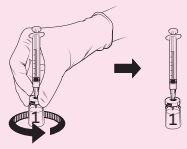
- Qdenga™ must not be administered by intravascular, intradermal or intramuscular injection
- The vaccine should not be mixed in the same syringe with any vaccines or other parenteral medicinal products, as per section 6.6 of the SmPC
- Use only the solvent provided for reconstitution
- Remove vial and pre-filled syringe from refrigerator and place at room temperature for approximately **15 minutes** before reconstitution

Step 1: Prepare



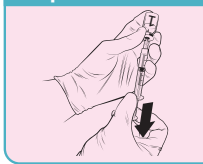
- Remove the cap from the vaccine vial and clean the surface of the stopper on top of the vial using an alcohol wipe
- Attach a sterile needle to the pre-filled syringe and insert the needle into the vaccine vial. **The recommended needle is 23G**
- Direct the flow of the solvent toward the side of the vial while slowly depressing the plunger to reduce the chance of forming bubbles

Step 2: Reconstitute



- Release your finger from the plunger and, holding the assembly on a flat surface, gently swirl the vial in both directions with the needle syringe assembly attached
- **DO NOT SHAKE.** Foam and bubbles may form in the reconstituted product
- Let the vial and syringe assembly sit for a while until the solution becomes clear. This takes about 30-60 seconds
- Following reconstitution, resulting solution should be clear, colourless to pale yellow. Discard if particulates are present and/or if it appears discoloured

Step 3: Administer



- Withdraw the entire volume of the reconstituted Qdenga™ solution with the same syringe until an air bubble appears in the syringe
- Remove the needle syringe assembly from the vial
- Hold the syringe with the needle pointing upward, tap the side of the syringe to bring the air bubble to the top, discard the attached needle and replace with a new sterile needle, then expel the air bubble until a small drop of the liquid forms at the top of the needle. **The recommended needle is 25G 16mm**
- Qdenga™ is now ready to be administered by **subcutaneous injection (SC)**, preferably in the deltoid region of the upper arm

2-dose schedule, 3 months apart[1]

1st dose
0.5 mL
Administer at Month 0

2nd dose
0.5 mL
Administer at Month 3

- **To receive the full benefit of protection from this vaccine, patients should receive both doses 3 months apart[1]**
- **Remember to encourage your patients to schedule their second dose after receiving their first dose**

Medical supervision must be readily available after dosing in the event of an anaphylactic reaction[1]

Refer to the Summary of Product Characteristics for details on full side effect profile and interactions.
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Qdenga™▼
Dengue Tetravalent Vaccine (Live, Attenuated)

Prescribing Information - Northern Ireland

Qdenga▼ (Dengue tetravalent vaccine - live, attenuated) powder and solvent for solution for injection in pre-filled syringe.
PRESCRIBING INFORMATION FOR NORTHERN IRELAND
Refer to Summary of Product Characteristics (SmPC) before prescribing

Presentation: After reconstitution, 1 dose (0.5 mL) contains: live, attenuated dengue virus serotype 1: ≥ 3.3 log10 PFU [Plaque-Forming Units]/dose; live, attenuated dengue virus serotype 2: ≥ 2.7 log10 PFU/dose; live, attenuated dengue virus serotype 3: ≥ 4.0 log10 PFU/dose; and live, attenuated dengue virus serotype 4: ≥ 4.5 log10 PFU/dose. This product is produced in Vero cells and contains genetically modified organisms (GMOs). **Indication**: Qdenga is indicated for the prevention of dengue disease in individuals from 4 years of age. **Dosage and administration**: Qdenga should be administered as a 0.5 mL dose at a two-dose (0 and 3 months) schedule. The need for a booster dose has not been established. Method of administration: After complete reconstitution of the lyophilised vaccine with the solvent, Qdenga should be administered by subcutaneous injection preferably in the upper arm in the region of deltoid. Qdenga must not be injected intravascularly, intradermally or intramuscularly. The vaccine should not be mixed in the same syringe with any vaccines or other parenteral medicinal products. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients or hypersensitivity to a previous dose of Qdenga. Individuals with congenital or acquired immune deficiency, including immunosuppressive therapies such as chemotherapy or high doses of systemic corticosteroids (e.g. 20 mg/day or 2 mg/kg body weight/day of prednisone for 2 weeks or more) within 4 weeks prior to vaccination, as with other live attenuated vaccines. Individuals with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function. Pregnant women. Breast-feeding women. **Warnings and precautions**: Traceability: Name and batch number of the administered product should be clearly recorded. Anaphylaxis: appropriate medical treatment and supervision must be readily available in the event of a rare anaphylactic reaction. Review of medical history: vaccination should be preceded by a review of the individual's medical history (especially with regard to previous vaccination and possible hypersensitivity reactions which occurred after vaccination). Concurrent illness: Vaccination with Qdenga should be postponed in subjects suffering from an acute severe febrile illness. Limitations of vaccine effectiveness: A protective immune response with Qdenga may not be elicited in all vaccinees against all serotypes of dengue virus and may decline over time. It is currently unknown whether a lack of protection could result in an increased severity of dengue. It is recommended to continue personal protection measures against mosquito bites after vaccination. There are no data on the use of Qdenga in subjects above 60 years of age and limited data in patients with chronic medical conditions. Anxiety-related reactions: 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. Women of childbearing potential: women of childbearing potential should avoid pregnancy for at least one month following vaccination. **Interactions:** Avoid vaccination with Qdenga for at least 6 weeks, and preferably 3 months, following treatment with immunoglobulins or blood products containing immunoglobulins, such as blood or plasma. Qdenga should not be administered to subjects receiving immunosuppressive therapies within 4 weeks prior to vaccination. Use with other vaccines: Concomitant administration of Qdenga with a hepatitis A vaccine and with a yellow fever vaccine in two different schedules has been evaluated in clinical studies performed in adults. Concomitant vaccines should be administered in separate syringes at different injection sites. **Fertility, pregnancy and lactation**: Qdenga is a live attenuated vaccine, therefore Qdenga is contraindicated during pregnancy. Qdenga is contraindicated during breast-feeding. No specific studies have been performed on fertility in humans. **Effects on ability to drive and use machines**: Qdenga has minor influence on the ability to drive and use machines. **Undesirable effects**: Very common (≥1/10): Upper respiratory tract infection, decreased appetite, irritability, headache, somnolence, myalgia, injection site pain, injection site erythema, malaise, asthenia, fever. Common (≥1/100 to <1/10): Nasopharyngitis, pharyngotonsillitis, arthralgia, injection site swelling, injection site bruising, injection site pruritus, influenza like illness. Other serious undesirable effects: Angioedema. **Refer to the SmPC for details on full side effect profile and interactions. Basic cost**: £68.75 per dose. **Legal classification**: POM. **Marketing authorisation number(s)**: EU/1/22/1699/005. **Business responsible for sale and supply**: Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. **PI approval code**: pi-02309. **Date of preparation**: February 2023.

Qdenga▼: this medicinal product is subject to additional monitoring. Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com

Reference: 1. Qdenga Summary of Product Characteristics.

C-APROM/NI/DENV/0001 August 2023

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Dengue Tetravalent Vaccine (Live, Attenuated)