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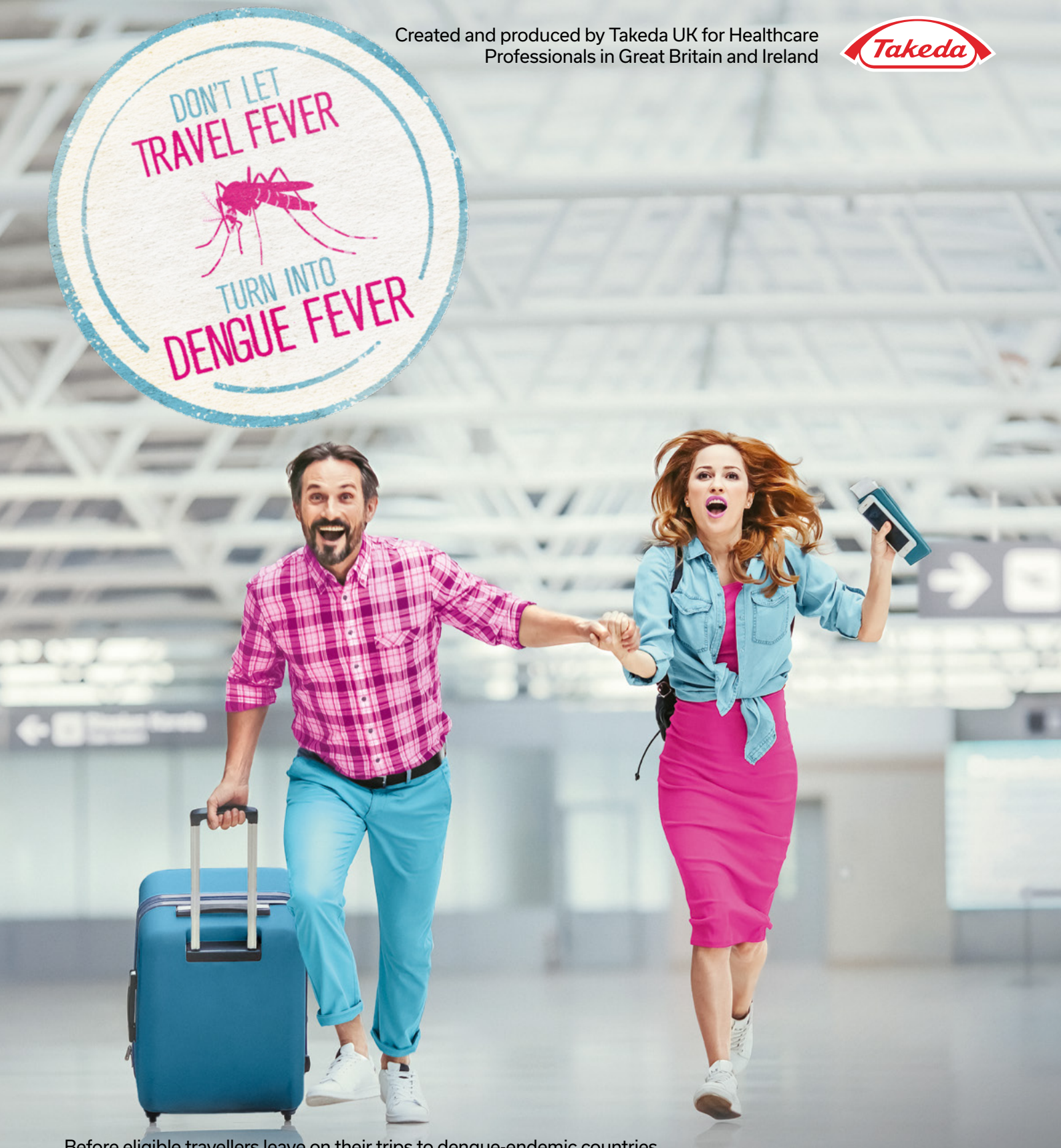


Before eligible travellers leave on their trips to dengue-endemic countries, help protect them against dengue, the fastest spreading mosquito-borne viral disease in the world.[1-5] It can cause illness that could ruin their trip, and even land them in the hospital.[4]

Qdenga™▼ (Dengue Tetravalent vaccine (Live, Attenuated)) 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.[1]

It's time to talk to eligible travellers about Qdenga™

Qdenga™▼
Dengue Tetravalent Vaccine (Live, Attenuated)

▼This medicinal product is subject to additional monitoring.
Prescribing information and adverse event reporting can be found on pages 8-10.

The more we know about dengue, the better we can help protect eligible travellers.

Consider starting a conversation with eligible travellers about dengue.

GIVEN DENGUE'S PREVALENCE AND RAPID SPREAD WORLDWIDE, STAYING INFORMED ABOUT PROTECTION AGAINST DENGUE IS MORE IMPORTANT THAN EVER.[6-8]

Dengue causes an estimated **390 MILLION INFECTIONS** and more than **20,000 DEATHS** globally each year.[3,4]

Worldwide, dengue cases are rising.[8] **ABOUT HALF THE WORLD'S POPULATION** now live in endemic areas.[4]

Dengue is a common mosquito-borne viral disease in endemic regions. Just one bite from a dengue-carrying mosquito could potentially result in illness and even hospitalisation.[4,9,10]

Many travellers who are exposed to dengue for the first time do not experience any symptoms. Though any infection can be severe, more often secondary infections become severe.[4]

Help travellers learn how to recognise symptoms

Dengue can sometimes be asymptomatic, but some of the common symptoms are[4]:

FEVER

SEVERE HEADACHE

JOINT AND MUSCLE PAIN

RASHES

NAUSEA AND VOMITING

PAIN BEHIND THE EYES

According to the World Health Organization, warning signs that indicate a severe dengue infection may include the following symptoms:[4]

- Severe abdominal pain
- Rapid breathing
- Fatigue and restlessness
- Persistent vomiting and blood in vomit or stool
- Bleeding in the gums or nose

Who's at risk of dengue, and what is the potential impact?

You could continue the conversation with travellers about who can get dengue, and how.

Travellers to many regions across Asia, Brazil, the Caribbean, and elsewhere are at risk of contracting dengue[11]

- Severe dengue in these areas is a cause of hospitalisation and death among children and adults[11]

Contrary to popular belief, dengue can be contracted anywhere in endemic regions—indoors, in urban or rural environments, and any time of day or year[12,13]

EXPLAIN THE POTENTIAL RISKS.

Each year, dengue haemorrhage fever and complications cause an estimated

20,000

fatalities and

500,000

hospitalisations worldwide.[11]

~42%
(n=2,119)

In one study, ~42% (n=2,119) of returning travellers who were ill with dengue had to be hospitalised.[14]

Dengue may be associated with long-term health consequences, including post-infection fatigue and a higher risk of autoimmune diseases.[15,16]

Many different travellers—all at potential risk

EVAN*

"My business trips are on a tight schedule. I can't afford any down time."

Evan, 46 years old, visits many different Asian cities on business. He's familiar with dengue and agrees that contracting it could be risky, but he thinks he is safe in a city and indoors.

Contrary to popular belief, you can contract dengue anywhere. This includes time spent indoors, in urban or rural environments, and any time of day or year.[12,13]

JAN AND OLLIE*

"We're excited to be taking a Caribbean cruise. But we worry about what could happen if we get infected."

Jan, 54 years old, and Ollie, 57, are happy to be traveling again. But they have certain health issues, so a severe infection could be dangerous.[3]

SYLVIA*

"The kids love visiting their cousins as often as possible. On one trip, they caught a fever. Was that dengue?"

Sylvia, 32 years old, and her children often visit family in Brazil, where dengue is endemic.

Dengue causes the most cases of febrile illness among people who need medical care after travel to Latin America or Asia—even more than malaria.[17]

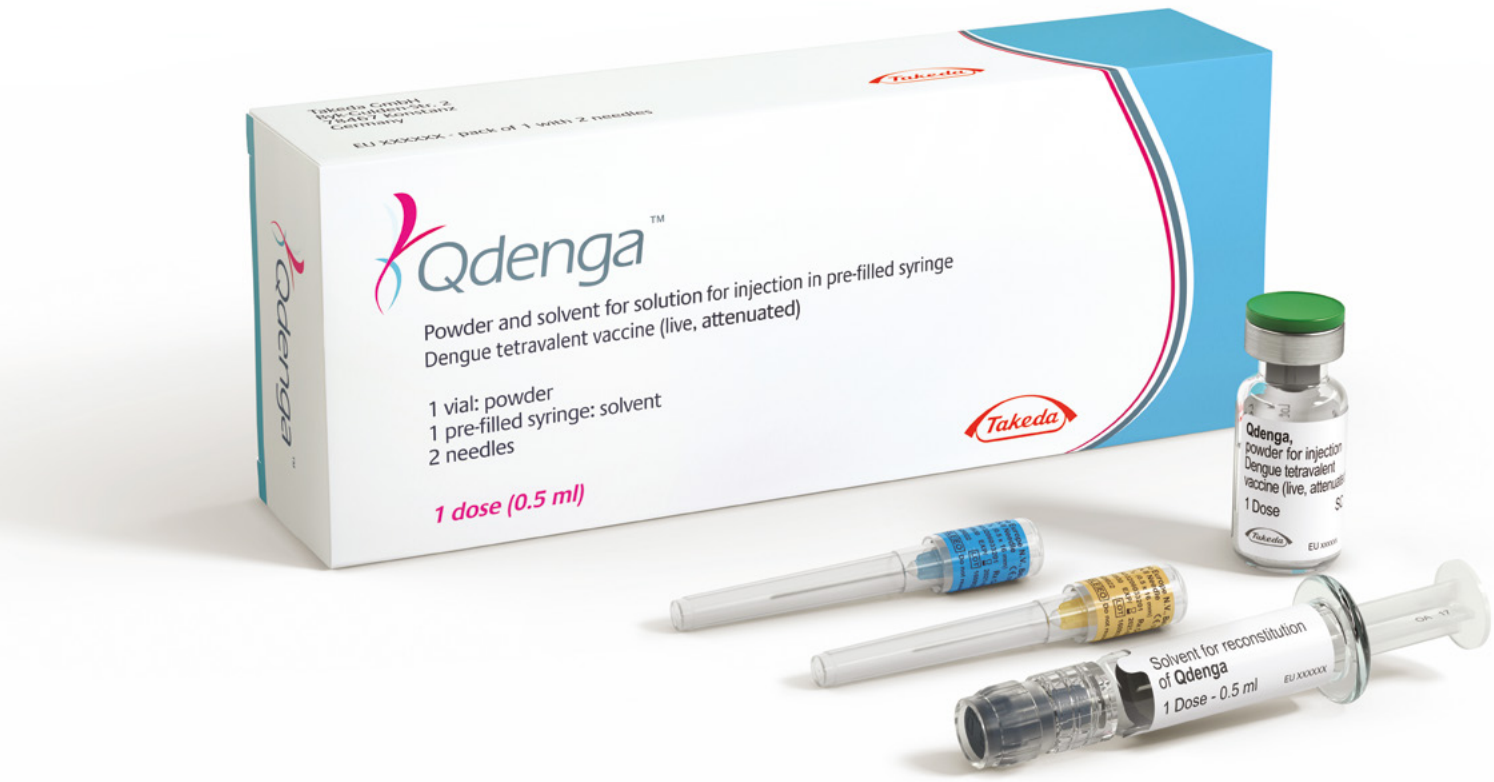
Qdenga™ is only licensed for individuals from 4 years of age.[1]

*Not an actual patient.

Help prevent dengue with Qdenga™ [1,18,19]

Consider discussing what protection is available, and when to receive it.

- Qdenga™ is a vaccine that may help protect against different strains of dengue, regardless of whether you have had dengue before or not[1]
- People from 4 years of age are eligible for the vaccine[1]
- Qdenga™ is proven to help prevent dengue and reduce hospitalisation[1,18,19]
- Qdenga™ is given as 2 subcutaneous injections, 3 months apart[1]
- No serostatus pretesting is required[1]
- Please refer to the Summary of Product Characteristics for full prescribing information



QDENGA™ OVERVIEW

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.[1]

Efficacy

- 80.2% (95% CI: 73.3-85.3) overall vaccine efficacy versus placebo from 30 days after the second dose until the end of the 12-month follow-up (primary endpoint)[1] (Qdenga™ n=12,700, placebo n=6316)[1,18*†]
- 90.4% (95% CI: 82.6-94.7) overall efficacy in preventing hospitalised dengue versus placebo from 30 days after the second dose until the end of the 18-month follow-up (secondary endpoint) (Qdenga™ n=12,700, placebo n=6316)[1,19*‡]

Sustained long-term 4.5 year exploratory analysis

- Qdenga™ demonstrated overall vaccine efficacy (VE) of 61.2% (95% CI: 56.0-65.8) against virologically confirmed dengue (VCD) versus placebo after the second dose (Qdenga™ n= 13,380, placebo n=6687).[1§] In baseline seropositive participants, efficacy against VCD was 64.2% (95% CI: 58.4, 69.2) versus placebo after the second dose (Qdenga™ n=9663, placebo n=4854). In baseline seronegative participants, efficacy against VCD was 53.5% (95% CI: 41.6, 62.9) versus placebo after the second dose (Qdenga™ n=3714, placebo n=1832). [1]
- Qdenga™ demonstrated sustained long-term overall efficacy against hospitalised dengue (84.1%; (95% CI: 77.8%, 88.6%)) versus placebo after the second dose (Qdenga™ n=13,380, placebo n=6687). In baseline seropositive participants, efficacy against hospitalised dengue was 85.9% (95% CI: 78.7, 90.7) versus placebo after the second dose (Qdenga™ n=9663, placebo n=4854). In baseline seronegative participants, efficacy against hospitalised dengue was 79.3% (95% CI: 63.5, 88.2) versus placebo after the second dose (Qdenga™ n=3714, placebo n=1832).[1]

Vaccine efficacy varied by individual serotype and serostatus at the end of the 18-month follow-up (secondary endpoint). Efficacy was shown for DENV-1, DENV-2, and DENV-3,[‖] but not for DENV-4 or severe dengue, largely due to the small number of cases (secondary endpoints). Data currently suggest a lack of efficacy against DENV-3 infection in baseline seronegative participants, but there is no evidence of disease enhancement.[1,19]

Safety

Qdenga™ is generally well tolerated with no identified important safety risks for up to 4.5 years.[1,18-20]

In clinical trials, the most frequently observed reactions were injection site pain, headache, myalgia, injection site erythema, malaise, asthenia, and fever.[1]

- Occurred within 2 days after the injection
- Were mild to moderate in severity
- Had a short duration (1 to 3 days)
- Were less frequent after the second injection

In one study, transient vaccine viremia was observed in 49% of participants who had not been infected with dengue before and in 16% of those who had been infected before. Vaccine viremia usually started in the second week after the first injection and had a mean duration of 4 days. It was rarely detected after the second dose. Symptoms were often mild to moderate, including headache, arthralgia, myalgia and rash in some subjects.[1]

Please refer to Summary of Product Characteristics for the most common adverse reactions, warnings and precautions, and contraindications.

*Based on a Phase 3, double-blind, randomised, placebo-controlled trial designed to evaluate the efficacy, safety, and immunogenicity of Qdenga™ in healthy children (4 to 16 years).[1]
†Incidence of cases: 0.5% Qdenga™ vs 2.4% placebo.[1]
‡Incidence of cases: 0.1% Qdenga™ vs 1.0% placebo.[1]
§The safety set consisted of all randomised subjects who received at least 1 dose of of Takeda's dengue tetravalent vaccine (live,attenuated) or placebo.[1]
‖DENV-1 (69.8% with 95% CI: 54.8, 79.9); DENV-2 (95.1% with 95% CI: 89.9, 97.6); DENV-3 (48.9% with 95% CI: 27.2, 64.1).[1]

Please go to pages 8-10 for Prescribing Information and Adverse Event reporting information.

PRESCRIBING INFORMATION - GREAT BRITAIN

Qdenga▼ (Dengue tetravalent vaccine - live, attenuated) powder and solvent for solution for injection in pre-filled syringe. PRESCRIBING INFORMATION FOR GREAT BRITAIN (ENGLAND, SCOTLAND, WALES)
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)**: PLGB 16189/0126. **Business responsible for sale and supply**: Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. **PI approval code**: pi-02275. **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

▼ This medicinal product is subject to additional monitoring.

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

▼ This medicinal product is subject to additional monitoring.

PRESCRIBING INFORMATION - REPUBLIC OF IRELAND

Qdenga▼ (Dengue tetravalent vaccine - live, attenuated) powder and solvent for solution for injection in pre-filled syringe. PRESCRIBING INFORMATION FOR REPUBLIC OF 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. 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Qdenga▼: this medicinal product is subject to additional monitoring. Adverse events should be reported to the Pharmacovigilance Unit at the Health Products Regulatory Authority. Regulatory forms and information can be found at www.hpra.ie . Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com

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Qdenga™ ▼
Dengue Tetravalent Vaccine (Live, Attenuated)

DON'T LET TRAVEL FEVER TURN INTO DENGUE FEVER

Recommend eligible travellers to vaccinate with Qdenga™

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.[1]

Created and produced by Takeda UK for Healthcare Professionals in Great Britain and Ireland

TO LEARN MORE VISIT
www.qdenga.co.uk

▼This medicinal product is subject to additional monitoring.
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C-APROM/GB/DENV/0105 | September 2023

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