
Qdenga™
Dengue Tetravalent Vaccine
(Live, Attenuated)
DENGUE DOESN'T DISCRIMINATE
It can infect people of all ethnicities, ages, and socioeconomic status.[1-3]
It's time to talk to your patients about Qdenga™.
Qdenga™ is indicated for the prevention of dengue disease caused by any dengue virus serotype in individuals 4 to 60 years of age.[4]
Start the conversation
Dengue is a viral disease that can affect anyone, regardless of age, socioeconomic status, or environment.[1-3] So it's important to discuss the risks of dengue with your patients and offer methods to help protect them.
Takeda

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The following questions and answers are designed to help you effectively engage with your patients.

Impact of dengue

Have you thought about how contracting dengue might impact your life or your family?

- While many patients with dengue will have mild symptoms or no symptoms at all, some may experience severe dengue. Severe dengue can involve fever, joint and muscle pain, and organ impairment that can lead to hospitalization and possibly death[1,5]
- Dengue symptoms can last 2 to 10 days. That means you or your kids may miss school, and you may need to take days or even weeks off of work after an infection[1,5,6]
- There is also evidence that dengue infections may lead to depression, anxiety, and stress even after physical symptoms have resolved[7]

Risk of severe dengue

Did you know that you may have already had dengue and having dengue more than once could put you at greater risk for severe dengue?

- More than 75% of people who have had dengue don't know it and some people get dengue more than once[1,8]
- Because dengue is caused by 4 distinct but related virus types, it is possible to be infected 4 times over the course of your lifetime[1]
- A second infection caused by a different type can increase the risk of severe dengue, which can potentially cause worse symptoms[1]

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Prevention with vaccination

Are you interested in a vaccine to help protect you and your family from dengue?

- Qdenga™ is a newly approved vaccine that may help protect you and your family against different strains of dengue, regardless of whether you have had dengue before or not.[4,9,10] People from 4-60 years of age are eligible for the vaccine[4]
- Qdenga™ is proven to help prevent dengue and reduce hospitalization[4,9,10]
- Qdenga™ is given as two injections, 3 months apart. It is important that you come back 3 months after your first dose for your second dose to receive the full benefit of this vaccine[4]

Safety and side effects

Do you have any concerns about the safety* and side effects of the vaccine for you or your children?

- Over the course of the Qdenga™ clinical trial program since 2016, more than 20,000 participants between 4 and 16 years of age have been vaccinated. Qdenga™ was generally well tolerated and there have been no important safety risks observed.†
- The most common side effect in both adults and children is pain at the injection site, usually lasting 1-3 days. Other common side effects in both adults and children include headache, muscle pain, malaise, and general fatigue[4]

Reduce the risks of being sick or missing work

Did you know that vaccination may help limit the financial impact of missing work or being hospitalized?

- Like any out-of-pocket vaccine, Qdenga™ is an investment in your health. Vaccination may help protect you from the potential impacts of missed work or hospitalization[5,6,11]

*Please refer to Full Product Information for the most common adverse reactions, warnings and precautions, and contraindications.
†At 36 months post second dose.

Patient Profiles

Qdenga™ Dengue Tetravalent Vaccine (Live, Attenuated)

Ana

"Will the buzzy things get me sick again?"

Ana, 8 years old, a student living in Valparaíso. Ana recently had dengue. She missed 10 days of school and has struggled to catch up with schoolwork due to lingering fatigue.

Past dengue infections may lead to depression, anxiety, and stress, even after the physical symptoms have resolved.[7]

Isabella

"I can't afford to miss any work."

Isabella, 38 years old, a middle-income mother of 3 living in São Paulo. She is aware that dengue poses a risk, but she doesn't know much about the disease.

Dengue symptoms last from 2 to 10 days and can force some people to miss work or school.[1,5,6]
Missed work can result in unexpected financial impact for individuals and entire families.[11]

Carlos

"Dengue symptoms could be serious."

Carlos, 51 years old, an upper middle-income father of one living in Mexico City. He is knowledgeable about dengue and understands that there is high risk of contracting it.

Symptoms can vary greatly, ranging from mild, undifferentiated fever to flu-like symptoms and joint and muscle pains. Although uncommon, severe cases can lead to organ impairment and/or plasma leakage, which may lead to death.[1]

A second infection caused by a different serotype can increase **the risk of severe dengue**.[1]

Meet more patients at www.qdenga.com/[XXX]

All profiles are of hypothetical patients.

Qdenga™ at a glance

Qdenga™ Dengue Tetravalent Vaccine (Live, Attenuated)

Indication

Qdenga™ is indicated for the prevention of dengue disease caused by any dengue virus serotype in individuals 4 to 60 years of age.[4]

Efficacy

- **80.2% overall vaccine efficacy** from 30 days after the second dose until the end of the 12-month follow-up (primary endpoint)[4,9*†]
- **90.4% overall efficacy in preventing hospitalized dengue** from 30 days after the second dose until the end of the 18-month follow-up (secondary endpoint)[4,10*‡]

Vaccine efficacy varied by individual serotype and serostatus at the end of the 18-month follow-up (secondary endpoint)[4,10]:

- 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[4,10]

Safety

- **Generally well tolerated[‖] with no important safety risk** observed and no evidence of enhanced disease severity in seronegative patients up to 3 years following the second dose, so no pretesting is required[4,9,10]
- In clinical trials, the most common adverse reactions were injection site pain, headache, myalgia, malaise, and asthenia[4]

Dosing

- Qdenga™ is administered as a 2-dose schedule, 3 months apart[4]

1st dose	2nd dose
0.5 mL	0.5 mL
Administer at Month 0	Administer at Month 3

*Based on a Phase 3, double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy, safety, and immunogenicity of Qdenga™ in healthy children (4 to 16 years).
†95% CI: 73.3, 85.3; *P*<0.001; Incidence of cases: 0.5% Qdenga™ vs 2.4% placebo.
‡95% CI: 82.6, 94.7; *P*<0.001; Incidence of cases: 0.1% Qdenga™ vs 1.0% placebo.
§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).

‖Please refer to Full Product Information for the most common adverse reactions, warnings and precautions, and contraindications.

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Dengue Tetravalent Vaccine (Live, Attenuated)

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 caused by any dengue virus serotype in individuals 4 years to 60 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 4 to 60 years of age at time of first injection:* 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/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:** Protective immune response may not be elicited in all vaccinees against all dengue serotypes. 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. Syncope (fainting) can occur especially in adolescents as a psychogenic response to the needle. Procedures should be in place to avoid injury from falling and to manage syncope. 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 aged 4 to 60 years of age were injection site pain (42%), headache (34%), myalgia (28%), malaise (23%), and asthenia (20%). Very common: (≥1/10 of subjects): decreased appetite[a], irritability[a], headache, somnolence[a], myalgia, injection site pain, malaise, asthenia. Common (≥1/100 to <1/10): viral upper respiratory tract infection, nasopharyngitis, pharyngotonsillitis[b], fever, injection site reactions (erythema, swelling). Uncommon (≥1/1,000 to <1/100): bronchitis, rhinitis, vomiting, diarrhoea, abdominal pain, rash[c], urticaria, arthralgia, injection site reactions (bruising, pruritus, haemorrhage), influenza-like illness. Rare (≥1/10,000 to <1/1,000): pruritus. **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:** May 2021.

Refer to the SmPC for details on full side effect profile and interactions.

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

[a] Collected in children 4-6 years of age in clinical studies.
[b] Includes pharyngotonsillitis and tonsillitis.
[c] Includes rash, viral rash, rash maculopapular, and rash pruritic.

References: 1. World Health Organization. Dengue and severe dengue. Updated June 23, 2020. Accessed March 25, 2021 https://www.who.int/en/news-room/fact-sheets/detail/dengue-and-severe-dengue **2.** Dantés HG, Farfán-Ale JA, Sarti E. Epidemiological trends of dengue disease in Mexico (2000–2011): a systematic literature search and analysis. *PLoS Negl Trop Dis*. 2014;8(11):e3158. Published November 6, 2014. doi:10.1371/journal.pntd.0003158 **3.** Constenla D, Armien B, Arredondo J, et al. Costing dengue fever cases and outbreaks: recommendations from a costing dengue working group in the Americas. *Value Health Reg Issues*. 2015;8:80-91. doi:10.1016/j.vhri.2015.06.001 **4.** QDENGA Summary of Product Characteristics. Takeda Vaccines, Inc, 2021. **5.** Bärnighausen T, Bloom DE, Cafiero ET, et al. Valuing the broader benefits of dengue vaccination, with a preliminary application to Brazil. *Semin Immunol*. 2013;25(2):104-113. doi:10.1016/j.smim.2013.04.010 **6.** Bansal P. Dengue fever with prolonged recovery - case report. *Ann Vaccines Immunization*. 2017;3(1):1014. **7.** Gunthalika N, Chandradasa M, Champika L, et al. Delayed anxiety and depressive morbidity among dengue patients in a multi-ethnic urban setting: first report from Sri Lanka. *Int J Ment Health Syst*. 2018;12:20. doi:10.1186/s13033-018-0202-6 **8.** Duong V, Lambrechts L, Paul RE, et al. Asymptomatic humans transmit dengue virus to mosquitoes. *Proc Natl Acad Sci U S A*. 2015;112(47):14688-14693. doi:10.1073/pnas.1508114112 **9.** Biswal S, Reynales H, Saez-Llorens X, et al; for the TIDES Study Group. Efficacy of a tetravalent dengue vaccine in healthy children and adolescents. *N Engl J Med*. 2019;381(21):2009-2019. doi:10.1056/NEJMoa1903869 **10.** Biswal S, Borja-Tabora C, Vargas LM, et al. Efficacy of a tetravalent dengue vaccine in healthy children aged 4-16 years: a randomised, placebo-controlled, phase 3 trial. *Lancet*. 2020;395(10234):1423-1433. doi:10.1016/S0140-6736(20)30414-1 **11.** Van Damme W, Van Leemput L, Por I, et al. Out-of-pocket health expenditure and debt in poor households: evidence from Cambodia. *Trop Med Int Health*. 2004;9(2):273-280. doi:10.1046/j.1365-3156.2003.01194.x

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