

QDENGGA

(Dengue Tetravalent Vaccine (Live, Attenuated) powder and solvent for solution for injection)

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What Qdenga is used for

Dengue Tetravalent Vaccine (Live, Attenuated) is a vaccine. It is used to help protect you or your child against dengue. Dengue is a disease caused by dengue virus serotypes 1, 2, 3 and 4. Dengue Tetravalent Vaccine (Live, Attenuated) contains weakened versions of these 4 dengue virus serotypes so it cannot cause dengue disease.

Dengue Tetravalent Vaccine (Live, Attenuated) is given to adults, young people and children (from 4 years of age).

Dengue Tetravalent Vaccine (Live, Attenuated) should be used according to official recommendations.

How Qdenga works

Dengue Tetravalent Vaccine (Live, Attenuated) stimulates the body's natural defences (immune system). This helps to protect against the viruses that cause dengue if the body is exposed to these viruses in the future.

Dengue is caused by a virus.

- The virus is spread by mosquitos (Aedes mosquitos).
- If a mosquito bites someone with dengue it can pass the virus on to the next people it bites.

Dengue is not passed directly from person to person.

Signs of dengue include fever, headache, pain behind the eyes, muscle and joint pain, feeling or being sick (nausea and vomiting), swollen glands or skin rash. Signs of dengue usually last for 2 to 7 days. You can also be infected with dengue virus but show no signs of illness.

Occasionally dengue can be severe enough for you or your child to have to go to hospital and in rare cases it can cause death. Severe dengue can give you a high fever and any of the following: severe abdominal (belly) pain, persistent sickness (vomiting), rapid breathing, severe bleeding, bleeding in the stomach, bleeding gums, feeling tired, feeling restless, coma, having fits (seizures) and organ failure.

Before you use Qdenga

- *When you must not use it*

If you or your child

- are allergic to the active substances or any of the other ingredients of Dengue Tetravalent Vaccine (Live, Attenuated).
- had an allergic reaction after receiving Dengue Tetravalent Vaccine (Live, Attenuated) before. Signs of an allergic reaction may include an itchy rash, shortness of breath and swelling of the face and tongue.
- have a weak immune system (the body's natural defences). This may be due to a genetic defect or HIV infection.
- are taking a medicine that affects the immune system (such as high-dose corticosteroids or chemotherapy). Your doctor will not use Dengue Tetravalent Vaccine (Live, Attenuated) until

sometime after you stop treatment with this medicine.

- are pregnant or breast-feeding.

- *Before you start to use it*

Tell your doctor, pharmacist or nurse before receiving Dengue Tetravalent Vaccine (Live, Attenuated) if you or your child:

- Have an infection with fever. It might be necessary to postpone the vaccination until recovery.
- Have ever had any health problems when given a vaccine. Your doctor will carefully consider the risks and benefits of vaccination.
- Have ever fainted from an injection. Dizziness, fainting, and sometimes falling, can happen (mostly in young people) following, or even before, any injection with a needle.

- *Taking other medicines*

Dengue Tetravalent Vaccine (Live, Attenuated) can be given with a hepatitis A vaccine, yellow fever vaccine or human papillomavirus vaccine at a separate injection site (another part of your body, usually the other arm) during the same visit.

Tell your doctor or pharmacist if you or your child are using, have recently used, or might use any other vaccines or medicines.

In particular, tell your doctor or pharmacist if you or your child are taking any of the following:

- Medicines that affect your body's natural defences (immune system) such as high-dose corticosteroids or chemotherapy. In this case, your doctor will not use Dengue Tetravalent Vaccine (Live, Attenuated) until sometime after you stop treatment. This is because Dengue Tetravalent Vaccine

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(Live, Attenuated) might not work as well.

- Medicines called “immunoglobulins” or blood products containing immunoglobulins, such as blood or plasma. In this case, your doctor will not use Dengue Tetravalent Vaccine (Live, Attenuated) until 6 weeks, and preferably not for 3 months after you stop treatment. This is because Dengue Tetravalent Vaccine (Live, Attenuated) might not work as well.

How to use Qdenga

- How much to use

Dengue Tetravalent Vaccine (Live, Attenuated) is given by your doctor or nurse as an injection under the skin (subcutaneous injection) in the upper arm. It must not be injected into a blood vessel.

You or your child will receive 2 injections. The second injection is given 3 months after the first injection.

There are no data in adults above 60 years of age. Ask your doctor for advice whether it is beneficial for you to receive Dengue Tetravalent Vaccine (Live, Attenuated) Takeda.

- When to use it

Dengue Tetravalent Vaccine (Live, Attenuated) should be used according to official recommendations.

- How long to use it

Dengue Tetravalent Vaccine (Live, Attenuated) should be used according to official recommendations.

- If you forget to use it

- If you or your child miss a scheduled injection, your doctor

will decide when to give the missed injection. It is important that you or your child follow the instructions of your doctor, pharmacist or nurse about the follow-up injection.

- If you forget or are not able to go back at the scheduled time, ask your doctor, pharmacist or nurse for advice.

- If you use too much (overdose)

- If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

While you are using it

- Things you must do

As with any vaccine, Dengue Tetravalent Vaccine (Live, Attenuated) Takeda may not protect everybody who receives it and protection might decrease over time. You may still get dengue fever from mosquito bites, including severe dengue illness. You must continue to protect yourself or your child against mosquito bites even after vaccination with Dengue Tetravalent Vaccine (Live, Attenuated).

After vaccination, you should consult a doctor if you or your child believe you might have a dengue infection, and develop any of the following symptoms: high fever, severe abdominal pain, persistent vomiting, rapid breathing, bleeding gums, tiredness, restlessness and blood in vomit.

You should take precautions to prevent mosquito bites. This includes using insect repellents, wearing protective clothing, and using mosquito nets.

- Things you must not do

Children less than 4 years of age must not receive Dengue

Tetravalent Vaccine (Live, Attenuated).

Do not use Dengue Tetravalent Vaccine (Live, Attenuated) if you or your daughter are pregnant or breast-feeding. If you or your daughter:

- are of child-bearing age, you must take necessary precautions to avoid pregnancy for one month after Dengue Tetravalent Vaccine (Live, Attenuated) vaccination.

- think you or your daughter may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before using Dengue Tetravalent Vaccine (Live, Attenuated).

- Things to be careful of

Dengue Tetravalent Vaccine (Live, Attenuated) has a minor influence on the ability to drive and use machines in the first days following vaccination.

Dengue Tetravalent Vaccine (Live, Attenuated) contains sodium and potassium.

Dengue Tetravalent Vaccine (Live, Attenuated) contains less than 1 mmol sodium (23 mg) per 0.5 mL dose, i.e. essentially “sodium-free”.

Dengue Tetravalent Vaccine (Live, Attenuated) contains less than 1 mmol potassium (39 mg) per 0.5 mL dose, i.e. essentially ‘potassium-free’.

Side effects

Like all medicines, Dengue Tetravalent Vaccine (Live, Attenuated) Takeda can cause side effects, although not everybody gets them.

Severe allergic (anaphylactic) reaction

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If any of these symptoms occur after leaving the place where you or your child received an injection, **contact a doctor immediately**:

- difficulty breathing
- blueness of the tongue or lips
- a rash
- swelling of the face or throat
- low blood pressure causing dizziness or fainting
- sudden and serious feeling of illness or unease with drop in blood pressure causing dizziness and loss of consciousness, rapid heartbeat linked with breathing difficulty.

These signs or symptoms (anaphylactic reactions) usually develop soon after the injection is given and while you or your child are still in the clinic or doctor's surgery. They can also happen very rarely after receiving any vaccine.

The following side effects occurred during studies in children, young people and adults.

Very common (may affect more than 1 in 10 people):

- injection site pain
- headache
- muscle pain
- injection site redness
- generally feeling unwell
- weakness
- infections of the nose or throat
- fever

Common (may affect up to 1 in 10 people):

- injection site swelling
- pain or inflammation of the nose or throat

- injection site bruising
- injection site itching
- inflammation of throat and tonsils
- joint pain
- flu like illness

Uncommon (may affect up to 1 in 100 people):

- diarrhoea
- feeling sick
- stomach pain
- being sick (vomiting)
- injection site bleeding
- feeling lightheaded
- itchy skin
- skin rash, including blotchy or itchy skin eruptions
- hives
- tiredness
- skin colour changes at the injection site
- inflammation of the airways
- runny nose

Rare (may affect up to 1 in 1,000 people):

- small red or purple spots under your skin (petechiae)

Very rare (may affect up to 1 in 10,000 people):

- rapid swelling under the skin in areas such as the face, throat, arms and legs
- low levels of blood platelets (thrombocytopenia)

Not known (cannot be estimated from the available data):

- sudden, severe allergic (anaphylactic) reaction, with breathing difficulty, swelling, lightheadedness, fast

heartbeat, sweating and loss of consciousness.

- eye pain

Additional side effects in children 4 to 5 years of age:

Very common (may affect more than 1 in 10 people):

- decreased appetite
- feeling sleepy
- irritability

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Qdenga

- Storage

Keep Dengue Tetravalent Vaccine (Live, Attenuated) out of the sight and reach of children.

Do not use Dengue Tetravalent Vaccine (Live, Attenuated) after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Keep the vaccine in the outer carton.

After mixing (reconstitution) with the solvent provided, Dengue Tetravalent Vaccine (Live, Attenuated) should be used immediately. If not used immediately, Dengue Tetravalent Vaccine (Live, Attenuated) must be used within 2 hours.

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- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

- What it looks like

Dengue Tetravalent Vaccine (Live, Attenuated) is a powder and solvent for solution for injection. Dengue Tetravalent Vaccine (Live, Attenuated) is provided as a powder in a single-dose vial and a solvent in a single-dose vial.

The powder and the solvent must be mixed together before use.

Dengue Tetravalent Vaccine (Live, Attenuated) powder and solvent for solution for injection is available in packs of 1 or 10.

Not all pack sizes might be marketed.

The powder is a white to off-white coloured compact cake.

The solvent (0.22% sodium chloride solution) is a clear, colourless liquid.

After reconstitution, Dengue Tetravalent Vaccine (Live, Attenuated) is a clear, colourless to pale yellow solution, essentially free of foreign particulates.

- Ingredients

- Active ingredient(s)

After reconstitution, one dose (0.5 mL) contains:

Dengue virus serotype 1 (live, attenuated)*: $\geq 3.3 \log_{10}$ PFU**/dose

Dengue virus serotype 2 (live, attenuated)*: $\geq 2.7 \log_{10}$ PFU**/dose

Dengue virus serotype 3 (live, attenuated)*: $\geq 4.0 \log_{10}$ PFU**/dose

Dengue virus serotype 4 (live, attenuated)*: $\geq 4.5 \log_{10}$ PFU**/dose

*Produced in Vero cells by recombinant DNA technology. Genes of serotype-specific surface proteins engineered into dengue type 2 backbone

#Produced in Vero cells by recombinant DNA technology.

**PFU = Plaque-forming units

- Inactive ingredients

• The other ingredients are: α, α -Trehalose dihydrate, Poloxamer 407, human serum albumin, potassium dihydrogen phosphate, disodium hydrogen phosphate, potassium chloride, sodium chloride, water for injections.

- MAL number:

MAL24026009ACZ

Manufacturer

DP vaccine manufacturer:
IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

DP vaccine manufacturer:
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Production Site Singen
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Product Registration Holder

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