Package leaflet: Information for the user

Qdenga powder and solvent for solution for injection in pre-filled syringe

Dengue tetravalent vaccine (live, attenuated)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you or your child is vaccinated because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Qdenga is and what it is used for

Qdenga 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. Qdenga contains weakened versions of these 4 dengue virus serotypes so it cannot cause dengue disease.

Qdenga is given to adults, young people and children (from 4 years of age).

Qdenga should be used according to official recommendations.

How the vaccine works
Qdenga 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.

What dengue is
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.

2. What you need to know before you or your child receive Qdenga

To make sure that Qdenga is suitable for you or your child, it is important to tell your doctor, pharmacist or nurse if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor, pharmacist or nurse to explain.

Do not use Qdenga if you or your child
- are allergic to the active substances or any of the other ingredients of Qdenga (listed in section 6).
- had an allergic reaction after receiving Qdenga 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 Qdenga until 4 weeks after you stop treatment with this medicine.
- are pregnant or breast-feeding.

Do not use Qdenga if any of the above applies.

Warnings and precautions
Tell your doctor, pharmacist or nurse before receiving Qdenga 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.

Important information about the protection provided
As with any vaccine, Qdenga 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 Qdenga.

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.

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

Younger children
Children less than 4 years of age must not receive Qdenga.

Other medicines and Qdenga
Qdenga can be given with a hepatitis A vaccine or yellow fever 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 Qdenga until 4 weeks after you stop treatment. This is because Qdenga 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 Qdenga until 6 weeks, and preferably not for 3 months after you stop treatment. This is because Qdenga might not work as well.

Pregnancy and breast-feeding
Do not use Qdenga 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 Qdenga 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 Qdenga.

Driving and using machines
Qdenga has a minor influence on the ability to drive and use machines in the first days following vaccination.

Qdenga contains sodium and potassium
Qdenga contains less than 1 mmol sodium (23 mg) per 0.5 mL dose, i.e. essentially 'sodium-free'.
Qdenga contains less than 1 mmol potassium (39 mg) per 0.5 mL dose, i.e. essentially 'potassium-free'.

3. How Qdenga is given

Qdenga 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 Qdenga.

Qdenga should be used according to official recommendations.

Instructions for preparing the vaccine intended for medical and healthcare professionals are included at the end of the leaflet.

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

4. Possible side effects

Like all medicines, Qdenga can cause side effects, although not everybody gets them.

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

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

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Qdenga

Keep Qdenga out of the sight and reach of children.

Do not use Qdenga 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, Qdenga should be used immediately. If not used immediately, Qdenga must be used within 2 hours.

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

6. Contents of the pack and other information

What Qdenga contains

- After reconstitution, one dose (0.5 mL) contains:
  Dengue virus serotype 1 (live, attenuated)*: ≥ 3.3 log10 PFU**/dose
  Dengue virus serotype 2 (live, attenuated)#: ≥ 2.7 log10 PFU**/dose
  Dengue virus serotype 3 (live, attenuated)*: ≥ 4.0 log10 PFU**/dose
  Dengue virus serotype 4 (live, attenuated)*: ≥ 4.5 log10 PFU**/dose

  *Produced in Vero cells by recombinant DNA technology. Genes of serotype-specific surface proteins engineered into dengue type 2 backbone. This product contains genetically modified organisms (GMOs).
  #Produced in Vero cells by recombinant DNA technology.
  **PFU = Plaque-forming units

- 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.

What Qdenga looks like and contents of the pack
Qdenga is a powder and solvent for solution for injection. Qdenga is provided as a powder in a single-dose vial and a solvent in pre-filled syringe with 2 separate needles or with no needle.
The powder and the solvent must be mixed together before use.

Qdenga powder and solvent for solution for injection in pre-filled syringe is available in packs of 1 or 5.

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, Qdenga is a clear, colourless to pale yellow solution, essentially free of foreign particulates.

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The following information is intended for healthcare professionals only:

- As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of Qdenga.
- Qdenga must not be mixed with other medicinal products or vaccines in the same syringe.
- Qdenga must not be administered by intravascular injection under any circumstances.
- Immunisation should be carried out by subcutaneous injection preferably in the upper arm in the region of the deltoid. Qdenga should not be administered by intramuscular injection.
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to injection with a needle. Procedures should be in place to prevent injury from falling and to manage syncopal reactions.

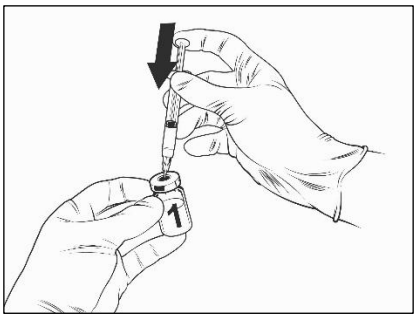
<u>Instructions for reconstitution of the vaccine with solvent presented in pre-filled syringe:</u>

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 solvent prior to administration.

Qdenga should not be mixed with other vaccines in the same syringe.

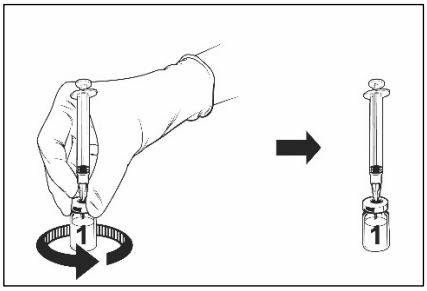
To reconstitute Qdenga, use only the solvent (0.22% sodium chloride solution) in the pre-filled syringe supplied with the vaccine since it is free of preservatives or other anti-viral substances. Contact with preservatives, antiseptics, detergents, and other anti-viral substances is to be avoided since they may inactivate the vaccine.

Remove the vaccine vial and pre-filled syringe solvent from the refrigerator and place at room temperature for approximately 15 minutes.



Lyophilised vaccine vial

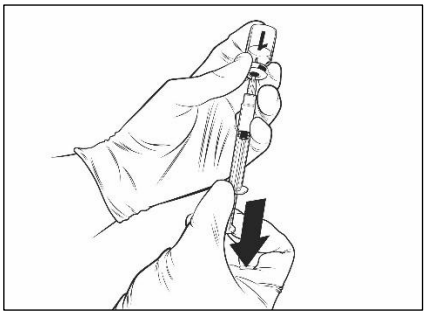
- Remove the cap from the vaccine vial and clean the surface of stopper on top of the vial using an alcohol wipe.
- Attach a sterile needle to the pre-filled syringe and insert the needle into the vaccine vial. The recommended needle is 23G.
- Direct the flow of the solvent toward the side of the vial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



Reconstituted vaccine

- 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, the resulting solution should be clear, colourless to pale yellow, and essentially free of foreign particulates. Discard the vaccine if particulates are present and/or if it appears discoloured.



Reconstituted vaccine

- 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 upwards, 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, expel the air bubble until a small drop of the liquid forms at the top of the needle. The recommended needle is 25G 16 mm.
- Qdenga is ready to be administered by subcutaneous injection.

Qdenga should be administered immediately after reconstitution. Chemical and physical in-use stability have been demonstrated for 2 hours at room temperature (up to 32.5°C) from the time of reconstitution of the vaccine vial. After this time period, the vaccine must be discarded. Do not return it to the refrigerator. From a microbiological point of view Qdenga should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Any unused product or waste material should be disposed of in accordance with local regulations.