

QDENGAR[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given QDENGAR?

QDENGAR is a vaccine that helps protect against dengue disease. The vaccine can be given to adults, adolescents and children from 4 years of age. QDENGAR contains live attenuated (weakened) versions of dengue virus serotypes 1, 2, 3 and 4. For more information, see Section [1. Why am I being given QDENGAR?](#) in the full CMI.

2. What should I know before I am given QDENGAR?

You should not be given QDENGAR if you have ever had a sudden or severe allergic reaction to the active ingredients of QDENGAR or to any of the ingredients in the vaccine (listed at the end of the CMI). Do not use if you have a very weak or poorly functioning immune

system due to other medical condition or genetic defect, or are on any medicines or treatments that impact your immune system. Check with your doctor if you have an infection with fever, have other medical conditions, take any other medicines, recently received any other vaccines, are pregnant or plan to become pregnant or are breast-feeding or plan to breastfeed. Talk to your doctor if you have ever fainted from any needle injection. For more information, see Section [2. What should I know before I am given QDENGGA?](#) in the full CMI.

3. What if I am taking other medicines or receiving other vaccines?

Some medicines may interfere with QDENGGA and affect how it works. Tell your doctor if you are taking any medicines that affect your body's natural defenses (such as high-dose corticosteroids, chemotherapies or any medicines called "immunoglobulins"). Tell your doctor or pharmacist if you have recently received any other vaccine. For more information, see Section [3. What if I am taking other medicines or receiving other vaccines?](#) in the full CMI.

4. How will I be given QDENGGA?

Your doctor or healthcare professional will inject the vaccine under the skin (subcutaneous injection) of your upper arm. You will receive the first dose, followed by a second dose 3 months after the first injection to complete the vaccination schedule.

More information can be found in Section [4. How will I be given QDENGGA?](#) in the full CMI.

5. What should I know after receiving QDENGGA?

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Keep to your follow up visit for the second QDENGGA injection to complete the vaccination schedule. ● Continue to protect yourself against mosquito bites even after vaccination with QDENGGA. ● Tell your doctor straight away if you: <ul style="list-style-type: none"> - do not feel well during or after having received the QDENGGA injection. - believe you might have a dengue infection or develop any signs or symptoms of dengue infection. ● If you are a woman of child-bearing age, take necessary precautions to avoid falling pregnant for one month after QDENGGA vaccination.
<p>QDENGGA CMI v1.0 Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful before you drive or use any

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	<p>machines until you know how QDENGGA affects you. QDENGGA</p>

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	<p>has a minor influence on the ability to drive and use machines in</p>

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	<p>the first days following vaccination.</p>

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Keep to your follow up visit for the second QDENGGA injection to complete the vaccination schedule. ● Continue to protect yourself against mosquito bites even after vaccination with QDENGGA. ● Tell your doctor straight away if you: <ul style="list-style-type: none"> - do not feel well during or after having received the QDENGGA injection. - believe you might have a dengue infection or develop any signs or symptoms of dengue infection. ● If you are a woman of child-bearing age, take necessary precautions to avoid falling pregnant for one month after QDENGGA vaccination.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● QDENGGA is normally stored in the doctor's clinic or in the

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	<p>pharmacy. If you need to store QDENGGA, keep QDENGGA in the</p>

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	<p>refrigerator between 2°C</p>

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Keep to your follow up visit for the second QDENGGA injection to complete the vaccination schedule. ● Continue to protect yourself against mosquito bites even after vaccination with QDENGGA. ● Tell your doctor straight away if you: <ul style="list-style-type: none"> - do not feel well during or after having received the QDENGGA injection. - believe you might have a dengue infection or develop any signs or symptoms of dengue infection. ● If you are a woman of child-bearing age, take necessary precautions to avoid falling pregnant for one month after QDENGGA vaccination.
	<p>to 8°C in the original package. Do not freeze.</p>

For more information, see Section [5. What should I know after receiving QDENGGA?](#) in the full CMI.

6. Are there any side effects?

Very common side effects: redness or pain at the injection site, headache, muscle pain, generally feeling unwell, weakness, infections of the nose or throat, fever and additionally reported in children < 6 years of age: reduced appetite, feeling sleepy, irritability. Common side effects: swelling, bruising or itching at the injection site, pain or inflammation of the nose or throat, inflammation of the tonsils, joint pain, flu-like symptoms. Unknown side effects: reduced number of blood platelets. Serious side effects: sudden signs and symptoms of a severe allergic reaction. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

QDENGGA (Q-Den-Ga)

Active ingredient(s): Dengue tetravalent vaccine

Consumer Medicine Information (CMI)

This leaflet provides important information about using QDENGGA.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about QDENGGA.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.takeda.com/en-au. Those updates may contain important information about the medicine and its use of which you should be aware.

Where to find information in this leaflet:

[1. Why am I being given QDENGGA?](#)

- [2. What should I know before I am given QDENGGA?](#)
- [3. What if I am using other medicines or receiving other vaccines?](#)
- [4. How will I be given QDENGGA?](#)
- [5. What should I know after receiving QDENGGA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given QDENGGA?

QDENGGA is a vaccine that helps protect against dengue disease. The vaccine can be given to adults, adolescents and children from 4 years of age. QDENGGA contains live attenuated (weakened) versions of dengue virus serotypes 1, 2, 3 and 4.

Dengue is a disease caused by dengue virus serotypes 1, 2, 3 and 4. The virus is spread by mosquitos (the *Aedes* mosquito). If a mosquito bites someone with dengue, it can pass the virus onto the next person it bites. Dengue is not passed directly from person-to-person.

QDENGGA works by stimulating the body's natural defenses (immune system) to produce protection against dengue virus if the body is exposed to dengue virus in the future.

Although QDENGGA contains live attenuated (weakened) versions of the Dengue viruses, they are too weak to cause dengue disease in healthy people.

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 to result in the need 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 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 should I know before I am given QDENGGA?

Warnings

Do not use QDENGGA if:

- you are allergic to QDENGGA or the active ingredients of QDENGGA or to any of the ingredients listed at the end of this leaflet.

Signs and symptoms of an allergic reaction may include rash, hives, itching on skin, swelling of the face, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing. Always check the ingredients to make sure you can use this vaccine.

- you have a very weak or poorly functioning immune system (the body's natural defenses). This may be due to other medical conditions (for example, HIV infection) or genetic defects.
- you are taking any medicine or receiving any treatment that affect the immune system (for example, high-dose corticosteroids or chemotherapies or immunoglobulin blood products).
- you are pregnant or breast-feeding.

If you are not sure whether you should be given QDENGGA, talk to your doctor.

Check with your doctor if you:

- have any allergies to any other vaccines or medicines or any other substances.
- have a severe infection with a high fever. It might be necessary to postpone the vaccination until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor about this before being vaccinated.
- have ever had any health problems when given a vaccine.
- have ever fainted following or even before any needle injection.

Your doctor will carefully consider the risks and benefits of vaccination.

As with any vaccine, QDENGGA may not protect all people who receive the vaccine, and protection might decrease over time.

Temporary, stress-related responses associated with the process of receiving your injection may occur. This may include dizziness, fainting, sweating, increased heart rate and/or anxiety. If you start to feel dizzy or faint at any time during the process of receiving your injection, let your doctor or healthcare professional know. Take actions to avoid falling and injuring yourself, such as sitting or lying down.

After receiving QDENGGA, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or planning to become pregnant.

Talk to your doctor if you are breastfeeding or planning to breastfeed.

QDENGGA is not recommended to be given to pregnant women or during breastfeeding.

Take necessary precautions to avoid falling pregnant for one month after QDENGGA vaccination.

Use in elderly

Ask your doctor for advice whether it is beneficial for you to receive QDENGGA.

There are no data for adults above 60 years of age.

Use in young children

Children less than 4 years of age must not receive QDENGGA.

3. What if I am using other medicines or receiving other vaccines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with QDENGGA and affect how it works.

Tell your doctor or pharmacist if you are taking or have recently taken any of the following:

- medicines that affect your body's natural defenses ("immunosuppressants"), such as high-dose corticosteroids or chemotherapies.
- treatment with "immunoglobulins" or blood products containing immunoglobulins, such as blood or plasma.

If you are taking or have recently taken any of these medicines, your doctor will wait for at least 4 weeks after the immunosuppressive medicines are stopped or at least 6 weeks (preferably 3 months) after the immunoglobulins are stopped before giving you QDENGGA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect QDENGGA.

Getting QDENGGA with other vaccines

QDENGGA can be given at the same time as hepatitis A vaccine, yellow fever vaccine or human papillomavirus vaccine using a separate syringe and at a separate injection site (another part of your body, usually the other arm).

Tell your doctor or pharmacist if you are being given or have recently received any other vaccines.

Your doctor, nurse or pharmacist will be able to tell you what to do if QDENGGA is to be given with another medicine or vaccine.

4. How will I be given QDENGGA?

QDENGGA is given as an injection just under the skin (subcutaneous injection) by your doctor or trained healthcare professional.

The doctor or healthcare professional will prepare the injection for you before you are given it.

If you have any concerns about this, talk to your doctor, nurse or pharmacist.

How much you will receive

You will receive two injections of QDENGGA (0.5 mL each dose). You will be given the first dose, followed by a second dose 3 months after the first injection to complete the vaccination schedule.

Your doctor or healthcare professional will schedule a follow-up visit for your second injection. It is important that you return at the scheduled time for your follow-up injection.

How QDENGGA is given

Your doctor or trained healthcare professional will inject the vaccine just under the skin in the upper arm.

The vaccine must not be given directly into the veins (intravascularly).

If you miss an appointment to receive QDENGGA

If you miss your scheduled QDENGGA injection, or if you are unable to go back at the scheduled time for your second injection, tell your doctor and arrange another visit as soon as possible.

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

If you are given too much QDENGGA

If you think that you have used too much QDENGGA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know after receiving QDENGGA?

Things you should do

Make sure you attend your follow-up visit with the doctor or clinic for the second QDENGGA injection.

It is important the second injection is given 3 months after the first injection. This will ensure the best effect of the vaccine in protecting you against Dengue.

As with all vaccines given by injection, there is a very small risk of a sudden or severe allergic reaction. See additional information under Section [6. Are there any side effects?](#)

Remind any doctor, nurse or pharmacist you visit that you have been given QDENGGA.

Continue to protect yourself against mosquito bites even after vaccination with QDENGGA.

This includes using insect repellents, wearing protective clothing, and using mosquito nets.

As with any vaccine, QDENGGA may not protect everybody who receives it and protection may decrease over time. You may still get dengue fever from mosquito bites.

Tell your doctor if you 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
- blood in vomit

Driving or using machines

Be careful before you drive or use any machines or tools until you know how QDENGGA affects you.

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

Make sure you know how you react to QDENGGA before you drive a car, operate machinery, or do anything that could be dangerous if you are unwell.

Looking after your medicine

QDENGGA will normally be stored at the doctor's clinic or in the pharmacy.

If you need to store QDENGGA, follow the instructions on the carton to take care of your vaccine properly.

- Keep QDENGGA in the refrigerator between 2°C to 8°C.
- Do not freeze QDENGGA. Freezing destroys the vaccine.
- Keep it where children cannot reach it.
- Keep QDENGGA in the original package.

Do not use QDENGGA after the expiry date. If the vaccine is given after the expiry date, it may not work.

Do not use QDENGGA if the packaging is torn or shows signs of tampering.

Getting rid of any unwanted vaccine

It is unlikely that you will be asked to dispose of QDENGGA. However, if you no longer need to be given this vaccine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicine, including vaccines, can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General disorders and administration site conditions:</p> <ul style="list-style-type: none">• pain, swelling, bruising, redness or itching around where the injection is given• headache• feeling generally unwell• fever• feeling weak• flu-like symptoms <p>Musculoskeletal disorders</p> <ul style="list-style-type: none">• muscle pain	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● joint pain <p>Respiratory and mouth disorders</p> <ul style="list-style-type: none"> ● pain or inflammation of the nose or throat ● inflammation of the tonsils ● infections of the nose or throat <p>Blood disorders</p> <ul style="list-style-type: none"> ● reduced number of blood platelets <p>Metabolic disorders</p> <ul style="list-style-type: none"> ● reduced appetite <i>(children < 6 years of age)</i> <p>Psychiatric disorders</p> <ul style="list-style-type: none"> ● feeling sleepy <i>(children < 6 years of age)</i> ● irritability <i>(children < 6 years of age)</i> 	

Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 759 539">Severe allergic (anaphylactic) reactions</p> <p data-bbox="204 573 759 904">If any of these symptoms occur after leaving the place where you or your child received an injection, contact a doctor immediately:</p> <ul data-bbox="204 943 759 1962" style="list-style-type: none"><li data-bbox="204 943 759 1003">● difficulty breathing<li data-bbox="204 1010 759 1115">● blueness of the tongue or lips<li data-bbox="204 1133 759 1193">● a rash<li data-bbox="204 1200 759 1305">● swelling of the face or throat<li data-bbox="204 1323 759 1496">● low blood pressure causing dizziness or fainting<li data-bbox="204 1514 759 1962">● 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.	<p data-bbox="810 432 1382 819">Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>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.</p>	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experienced, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

QDENGGA is only available with a doctor's prescription.

What QDENGGA contains

Active ingredients (main ingredients)	Live attenuated (weakened) versions of dengue virus serotype 1, dengue virus serotype 2, dengue virus serotype 3, dengue virus serotype 4
Other ingredients (inactive ingredients)	trehalose dihydrate poloxamer albumin monobasic potassium phosphate dibasic sodium phosphate dihydrate potassium chloride sodium chloride water for injections

Each dose of QDENGGA (0.5 mL) contains:

- not less than 3.3 log₁₀ plaque-forming units (PFU) of dengue virus serotype 1
- not less than 2.7 log₁₀ PFU of dengue virus serotype 2

- not less than 4.0 log₁₀ PFU of dengue virus serotype 3
- not less than 4.5 log₁₀ PFU of dengue virus serotype 4

Do not receive this vaccine if you are allergic to any of these ingredients.

The vaccine was produced in Vero cells by recombinant DNA technology.

What QDENGGA looks like

QDENGGA is a powder and solvent for injection, which must be mixed by your doctor or healthcare professional together before use.

The vaccine powder is a white to off-white coloured compact cake, provided in single-dose glass vials with green flip-off caps.

The solvent (0.22% sodium chloride solution) is a clear and colourless liquid, provided in either pre-filled syringes or glass vials with purple flip-off caps.

After the vaccine powder is mixed with the solvent to make a solution suitable for injection, QDENGGA is a clear, colourless to pale yellow solution, essentially free of foreign particulates.

Australian Registration Numbers:

AUST R 506646: vaccine powder vial + solvent pre-filled syringe (with needles)

- pack of 1: containing 1 vial of vaccine powder and 1 pre-filled syringe of solvent, with 2 separate needles

AUST R 484846: vaccine powder vial + solvent vial
(without needles)

- pack of 1: containing 1 vial of vaccine powder and 1 vial of solvent
- pack of 10: containing 10 vials of vaccine powder and 10 vials of solvent

Not all presentations may be available.

Who distributes QDENGGA

QDENGGA is supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39 225 George Street
Sydney, NSW 2000
Australia

Telephone: 1800 012 612

www.takeda.com/en-au

This leaflet was prepared in April 2026.

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