

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I or my child being given VAQTA?

VAQTA contains hepatitis A virus protein which is an inactivated virus and is injected into the body. VAQTA is a vaccine used to help prevent hepatitis A. It can be given to children 12 months of age and older, teenagers and adults.

For more information, see Section [1. Why am I or my child being given VAQTA?](#) in the full CMI.

### 2. What should I know before my child or I are given VAQTA?

Do not use if you or your child have ever had an allergic reaction to VAQTA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before my child or I are given VAQTA?](#) in the full CMI.

### 3. What if my child or I are taking other medicines?

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

A list of these medicines is in Section [3. What if my child or I are taking other medicines?](#) in the full CMI.

### 4. How is VAQTA given?

A doctor or nurse will give you or your child this vaccine as an injection, usually into the upper arm.

The vaccine should not be injected directly into veins (intravenously).

More instructions can be found in Section [4. How is VAQTA given?](#) in the full CMI.

### 5. What should I know after my child or I have been given VAQTA?

Things you should do	<ul style="list-style-type: none"><li>It is important to return at the scheduled date for the follow-up dose</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know whether VAQTA has affected you.</li><li>VAQTA should not normally interfere with your ability to drive a car or operate machinery. However, VAQTA may cause tiredness or weakness in some people.</li></ul>
Looking after your medicine	<p>It is unlikely that you will be asked to store VAQTA. If you are:</p> <ul style="list-style-type: none"><li>Keep it where children cannot reach it.</li><li>Keep it in the refrigerator (not in the door compartment) between 2°C and 8°C. Do not freeze this vaccine.</li></ul>

For more information, see Section [5. What should I know after my child or I have been given VAQTA?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include: local reaction around the injection site such as pain, soreness, tenderness, warmth, redness or swelling; fever, sore throat, runny nose, cough, stomach pain, feeling sick (nausea), vomiting, diarrhoea, headache

Serious side effects may include allergic reactions such as skin rash; itching; or hives (pinkish, itchy swellings on the skin).

For a complete list of side effects and more information, including what to do if you or your child have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

## Consumer Medicine Information (CMI)

This leaflet provides important information about using VAQTA. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VAQTA.

### Where to find information in this leaflet:

- [1. Why am I or my child being given VAQTA?](#)
- [2. What should I know before my child or I are given VAQTA?](#)
- [3. What if my child or I are taking other medicines?](#)
- [4. How is VAQTA given?](#)
- [5. What should I know after my child or I are given VAQTA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I or my child being given VAQTA?

VAQTA is a vaccine used to help prevent hepatitis A. It can be given to children 12 months of age and older, teenagers and adults.

#### What is Hepatitis A

Hepatitis A is an infection of the liver caused by the hepatitis A virus. It can be caught by coming into contact with an infected person who has poor sanitary habits, eating or drinking foods prepared by an infected food handler, or, while uncommon, by blood transfusion from an infected donor. Other circumstances that can increase the risk of infection include:

- travelling to areas where hepatitis A is common
- living in a community with one or more recorded outbreaks within the last five years
- being around groups of other children, for example, daycare centres
- living in the same house as someone who is infected
- having chronic liver disease or having had a liver transplant
- sexual contact with someone who is infected
- being infected with Human Immunodeficiency Virus (HIV)
- working in the healthcare field
- eating raw shellfish
- sharing needles for injecting drugs
- having a blood disorder requiring transfusion of blood products.

Symptoms of hepatitis A usually begin 2 to 8 weeks after coming into contact with the virus. These include loss of appetite, feeling sick (nausea), vomiting, fever, chills, tiredness, yellowing of the skin and/or eyes and dark urine. Most people recover completely from hepatitis A

disease. However, occasionally cases develop into severe disease and death.

Hepatitis A occurs in Australia and New Zealand, but is not common. However, it is very common in many parts of the world and the risk of infection is greatest in those areas where hygiene and sanitation are poor. Immunisation against hepatitis A is suggested for travellers to such areas, including Asia, India, Africa, Central and South America.

#### How does it work

The vaccine contains inactivated virus and is injected into the body. The body then produces its own protection by making disease-fighting substances (antibodies) to fight the virus. The vaccine itself cannot cause the infection. If a vaccinated person comes into contact with live virus the body is usually ready, and produces antibodies to destroy it. However, as with all vaccines, 100% protection against hepatitis A cannot be guaranteed.

Because hepatitis A infection can go undetected for a long period of time, it is possible that an individual may already be infected at the time the vaccine is given. The vaccine may not prevent hepatitis A in these individuals.

VAQTA will not protect against hepatitis caused by other agents or viruses (such as hepatitis B, hepatitis C, hepatitis D, hepatitis E).

### 2. What should I know before my child or I are given VAQTA?

#### Warnings

##### Do not get VAQTA if:

- you or your child are allergic to VAQTA, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- the expiry date on the pack has passed. If the vaccine is used after the expiry date has passed, it may not work.

If you are not sure whether you or your child should be given VAQTA, talk to your doctor.

Do not give VAQTA to children under 12 months of age.

##### Check with your doctor if you or your child:

- have any medical conditions, especially the following:
  - bleeding problems
  - diseases which decrease the immune system, for example, AIDS
  - cancer

VAQTA may not work as well as it should if you or your child have diseases or conditions which decrease the body's immune defence system. Your doctor will decide whether or not to give the vaccine.

- **have an acute infection or a high temperature**  
Your doctor may decide to delay your injection of VAQTA.
- **have any allergies to any other medicines or any other substances, such as foods, preservatives, latex rubber or dyes.**

If you have not told your doctor about any of the above, tell them before you or your child are given an injection of VAQTA.

During treatment, 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 intend to become pregnant. It is not known whether the vaccine is harmful to an unborn baby when administered to a pregnant woman. Your doctor will give you VAQTA only if it is clearly needed.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether VAQTA passes into breast milk. Your doctor will discuss the possible risks and benefits of you being given VAQTA while breast-feeding.

### Use in Children

Do not give VAQTA to children under 12 months of age.

The safety and effectiveness of VAQTA in these children have not been established.

## 3. What if my child or I are taking other medicines?

**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.**

VAQTA may not work as well as it should if you or your child are taking medicines that decrease the immune system, such as corticosteroids (e.g. prednisone) or cyclosporin.

Your doctor will advise you if you are taking any of these or other medicines that decrease the immune system. Your doctor will decide whether or not to give the vaccine.

### Use with other vaccines

VAQTA may be given at the same time as yellow fever, typhoid, measles, mumps, rubella, varicella and pneumococcal 7-valent conjugate vaccines. VAQTA may also be given at the same time as an immune globulin injection. The injections should be given at different places on the body and using separate syringes.

There is limited information available regarding the administration of other vaccines at the same time as VAQTA. Your doctor will decide if VAQTA should be given with other vaccines.

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

## 4. How is VAQTA given?

### How much will you be given

Your doctor will decide on the dose of VAQTA that you will be given. This depends on your age.

- The usual dose for children and teenagers (12 months through 17 years of age) is 0.5 mL (approx. 25U).
- The usual dose for adults (18 years and older) is 1.0 mL (approx. 50U).

### How is it given

- VAQTA is given as an injection, usually into your upper arm muscle by a doctor or trained nurse.
- The vaccine should not be injected directly into veins (intravenously).

### Vaccination Schedule

VAQTA is generally given as a total of two doses. Each dose is given on a separate visit.

The schedule for children and teenagers (12 months to 17 years) is:

- 1st dose: at elected date
- 2nd dose: 6 to 18 months later

The schedule for adults is:

- 1st dose: at elected date
- 2nd dose: 6 to 18 months later

The schedule for adults infected with HIV is:

- 1st dose: at elected date
- 2nd dose: 6 months later

It is important to return at the scheduled date for the follow-up dose.

If you have been given another hepatitis A vaccine as your 1st dose, VAQTA may be given as the 2nd dose, 6 to 12 months later.

## 5. What should I know after my child or I have been given VAQTA?

### Things you should do

**Keep your follow-up appointment with your doctor or clinic.**

It is important to have your follow-up dose of VAQTA at the appropriate time to make sure the vaccine has the best chance of providing protection against the hepatitis A virus.

Remind any doctor, dentist or pharmacist you visit that you are using VAQTA.

### Driving or using machines

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

VAQTA should not normally interfere with your ability to drive a car or operate machinery. However, VAQTA may cause tiredness or weakness in some people. Make sure you know how you react to VAQTA before you drive a car, operate machinery, or do anything else that could be dangerous if you are tired or weak.

### Looking after your medicine

It is unlikely that you will be asked to store VAQTA.

However if you need to store VAQTA:

- Keep it where children cannot reach it.
- Keep it in the refrigerator, but not in the door compartment.
- Do not put VAQTA in the freezer, as freezing destroys the vaccine.
- Keep the injection in the original pack until it is time for it to be given.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you or your child 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, nurse, or pharmacist if you have any further questions about side effects.

### Common side effects in Children, Teenagers and Adults

Common side effects	What to do
<ul style="list-style-type: none"> <li>• Local reaction around the injection site such as pain, soreness, tenderness, warmth, redness or swelling</li> <li>• Fever, sore throat, runny nose, cough</li> <li>• Stomach pain, feeling sick (nausea), vomiting, diarrhoea</li> <li>• Headache</li> </ul> <p>These are the more common side effects of VAQTA that may occur in children, teenagers and adults. For the most part these have been mild.</p>	<p><b>Speak to your doctor if you or your child have any of these side effects and they worry you.</b></p>

### Common side effects in children 12 months to 23 months of age

Common side effects	What to do
<ul style="list-style-type: none"> <li>• Skin rash</li> <li>• Irritability, crying</li> <li>• Loss of appetite</li> </ul>	<p><b>Speak to your doctor if your child has any of</b></p>

Common side effects	What to do
<ul style="list-style-type: none"> <li>• Discharge with itching of the eyes and crusty eyelids</li> <li>• Infection of the ear, which may cause temporary hearing loss and pain</li> </ul> <p>These are the more common side effects of VAQTA that have been reported in children aged 12 months to 23 months.</p>	<p><b>these common side effects and they worry you.</b></p>

### Additional common side effects in adults

Common side effects	What to do
<ul style="list-style-type: none"> <li>• Tiredness, generalised weakness</li> <li>• Aching muscles, muscle tenderness, arm pain</li> </ul> <p>These are other mild side effects of VAQTA that have been reported in adults.</p>	<p><b>Speak to your doctor if you have any of these common side effects and they worry you.</b></p>

### Serious side effects in children/teenagers 2 years to 17 years of age and adults 18 years of age and older

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Muscle weakness</li> <li>• Loss of coordination, unsteadiness when walking</li> <li>• Bleeding or bruising more easily than normal</li> <li>• Headache and fever, progressing to hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light</li> </ul> <p>These may be serious side effects. You may need urgent medical attention.</p> <p><b>Allergic Reactions</b></p> <ul style="list-style-type: none"> <li>• Skin rash, itching</li> <li>• Hives or nettlerash (pinkish, itchy swellings on the skin)</li> </ul> <p>These may be signs of an allergic reaction to VAQTA. These side effects are rare.</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you or your child experience any of these serious side effects.</b></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 experience, you can report side effects to the

Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What VAQTA contains

<b>Active ingredient (main ingredient)</b>	Hepatitis A virus protein
<b>Other ingredients (inactive ingredients)</b>	Aluminium (as amorphous aluminium hydroxyphosphate sulfate) Borax Sodium chloride

**Do not take this medicine if you are allergic to any of these ingredients.**

VAQTA is made without any human blood or blood products. It does not contain any infectious material.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

### What VAQTA looks like

VAQTA comes in glass vials and prefilled syringes. It is a white milky liquid. Two different vaccine doses are available:

- approximately 25 Units in 0.5 mL of liquid
- approximately 50 Units in 1 mL of liquid

In the injection vial products, the vial stopper contains dry natural latex rubber.

In the injection syringe products, the syringe plunger stopper and tip cap are not made with natural rubber latex.

### Australian Register Numbers:

VAQTA hepatitis A vaccine inactivated 25 units/0.5mL injection vial (AUST R 58534)

VAQTA hepatitis A vaccine inactivated 50 units/1mL injection vial (AUST R 58536)

VAQTA hepatitis A vaccine inactivated 25 units/0.5mL injection syringe (AUST R 58539)

VAQTA hepatitis A vaccine inactivated 50 units/1mL injection syringe (AUST R 58540)

### Who distributes VAQTA

Merck Sharp & Dohme (Australia) Pty Ltd

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Macquarie Park NSW 2113

<http://www.msd-australia.com.au>

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