Package leaflet: Information for the user

VAQTA® Paediatric 25 U/0.5 mL, Suspension for injection in a pre-filled syringe
Hepatitis A vaccine, inactivated, adsorbed
For children and adolescents

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 vaccine 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 VAQTA 25 U/0.5 mL is and what it is used for

VAQTA 25 U/0.5 mL is a vaccine. Vaccines are used to protect against infectious diseases. They work by causing the body to produce its own protection against the targeted disease.

VAQTA 25 U/0.5 mL helps to protect children from 12 months old up to 17 years old against disease caused by hepatitis A virus.

Hepatitis A infection is caused by a virus that attacks the liver. It may be caught from food or drink that contains the virus. Symptoms include jaundice (yellowing of the skin and eyes) and feeling generally unwell.

When you or your child is given an injection of VAQTA 25 U/0.5 mL, the body's natural defences will start to produce protection (antibodies) against the hepatitis A virus. However, it usually takes 2 to 4 weeks after receiving the injection before you or your child will be protected.

VAQTA 25 U/0.5 mL will not prevent hepatitis caused by infectious agents other than hepatitis A virus.

Additionally, if you or your child is already infected with hepatitis A virus when VAQTA 25 U/0.5 mL is given, the vaccination may not prevent the illness.

VAQTA 25 U/0.5 mL protects against hepatitis A but cannot cause a hepatitis A infection.

2. What you need to know before VAQTA 25 U/0.5 mL is given

It is important to tell your doctor or nurse if any of the following points applies to you. If there is anything you do not understand, ask your doctor or nurse to explain.

VAQTA 25 U/0.5 mL should not be given

- if you or your child is allergic to the active substance or any of the other ingredients of VAQTA 25 U/0.5 mL (listed in section 6) or to neomycin or formaldehyde (see section "Talk to your doctor, pharmacist or nurse before VAQTA 25 U/0.5 mL is given").

- if you or your child currently has a serious infection with fever. Your doctor will decide when the vaccine can be administered.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before VAQTA 25 U/0.5 mL is given

- if you or your child has ever had an allergic reaction to a previous dose of VAQTA 25 U/0.5 mL.

- this vaccine may contain traces of an antibiotic called neomycin and a substance called formaldehyde, both of which are used during vaccine production and may be present in the vaccine in trace amounts.

- if you or your child has had any blood clotting problems resulting in easy bruising, or bleeding for a long time after minor cuts (for instance due to a bleeding disorder or treatment with blood thinning medicines).

- if you or your child has a weakened immune system, due to cancer, treatments that affect the immune system, or any other illness. The vaccine may not protect as well as it protects people whose immune system is healthy. If possible, it is recommended that vaccination is postponed until the end of such disease or treatment.

As with other vaccines, VAQTA 25 U/0.5 mL may not completely protect all persons who are vaccinated.

Please tell your doctor if you or your child has had a history of jaundice or have lived in an area where hepatitis A is common. Your doctor will determine whether you or your child should be tested for hepatitis A antibodies prior to vaccination.

Other medicines and VAQTA 25 U/0.5 mL

Tell your doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines (or other vaccines).

<u>Other vaccines</u>

As VAQTA 25 U/0.5 mL does not contain any live bacteria or viruses, it can generally be given at the same time as other vaccines but at a different injection site (another part of your body, e.g. the other arm or leg). VAQTA 25 U/0.5 mL must not be mixed with any other vaccine in the same syringe. Studies have demonstrated that VAQTA 25 U/0.5 mL may be given at the same time as measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate, inactivated polio, diphtheria toxoid, tetanus toxoid, acellular pertussis, and *Haemophilus influenzae* b vaccines.

In adults, VAQTA may be given at the same time as yellow fever and polysaccharide typhoid vaccines.

Immunoglobulin (antibodies)

Sometimes, a human immunoglobulin (antibodies) injection will be given to try and protect you or your child until the vaccine starts to work. VAQTA 25 U/0.5 mL may be given at the same time as human immunoglobulin (antibodies) provided that the two injections are given at different injection sites.

Medicines affecting the immune system or the blood

Please refer to the section "Warnings and precautions" above.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you or your child may be pregnant or is planning to have a baby, ask your doctor or pharmacist for advice whether you or your child should receive the vaccine.

Driving and using machines

There are no data to suggest that VAQTA 25 U/0.5 mL affects the ability to drive or operate machinery.

VAQTA contains sodium
This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium free'.

3. How VAQTA 25 U/0.5 mL is given

Dosage

VAQTA 25 U/0.5 mL should be given as an injection by doctors or nurses who are trained in the use of vaccines and who are equipped to deal with any uncommon severe allergic reaction. The person to be vaccinated will receive a first dose followed by a second (booster) dose.

First dose

Children from 12 months to 17 years of age should receive an injection of a single 0.5 mL dose (25 U). The first dose of vaccine should protect you or your child from infection with hepatitis A virus within 2 to 4 weeks.

Safety and effectiveness in infants <12 months of age have not been established.

Second (Booster) dose

Individuals having received the first dose of vaccine should receive the second (booster) dose of 0.5 mL (25 U) 6 to 18 months later.

Long term protection requires a second dose (booster dose) of the vaccine. Healthy children who have had two doses have been found to have antibody levels for at least 10 years. It is predicted that hepatitis A antibodies will remain at least 25 years after vaccination.

VAQTA 25 U/0.5 mL is not recommended for individuals older than 18 years of age.

Method of administration

Your doctor or nurse will give you or your child VAQTA 25 U/0.5 mL as an injection into a muscle in the upper part of the arm (deltoid muscle). The muscle in the outer thigh region may be used in children if the deltoid muscle is not sufficiently developed.

People who are at risk of bleeding a lot after an injection (e.g. haemophiliacs) may receive VAQTA 25 U/0.5 mL as an injection under the skin but not into the muscle to reduce the risk of bleeding.

VAQTA 25 U/0.5 mL must not be given into a blood vessel.

4. Possible side effects

Like all medicines and vaccines, VAQTA 25 U/0.5 mL can cause side effects, although not everybody gets them.

As with all vaccines, allergic reactions, in rare cases leading to shock, may occur. These reactions may include:
- hives
- difficulty in breathing
- swelling of the face, tongue and throat
- dizziness
- collapse

When these signs or symptoms occur they usually develop very quickly after the injection is given and while you or your child is still in the clinic or doctor's surgery. **If any of these symptoms occur after leaving the place where you or your child received the injection, contact a doctor IMMEDIATELY.**

Side effects reported in children aged 12 months to 23 months

Frequency of side effects	**Side effects**
Very common: may affect more than 1 in 10 children	injection-site pain/tenderness and injection-site redness
Common: may affect up to 1 in 10 children	- injection-site swelling, injection-site warmth, injection-site bruising - fever - irritability - diarrhea
Uncommon: may affect up to 1 in 100 children	- decreased or loss of appetite - trouble sleeping, sleepiness, feeling of tiredness-drowsiness, or lack of energy, restlessness - crying - runny nose, cough, nasal congestion - vomiting - rash, diaper rash - feeling unwell - injection-site lump, injection-site rash

Rare: may affect up to 1 in 1,000 children	- multiple allergies - dehydration - agitation, nervousness, fear, screaming - dizziness, headache, loss of balance - eyelid margin crusting - asthma, blocked airways, sneezing, runny or itchy nose, mouth and throat pain - nausea, stomach pain/discomfort, excessive gas in the stomach or bowel, frequent bowel movements, belching, infantile spitting up, constipation, discoloured faeces - rash, itching and redness of the skin, blisters, clammy or warm skin, sweating - inflamed joints - at injection-site: bleeding, itching, discoloration, lump formation or an itchy rash; pain, discomfort - fatigue, abnormality with manner of walking, feeling hot
Not known: frequency cannot be estimated from the available data	- Guillain-Barré syndrome (muscle weakness, abnormal sensations, tingling in the arms, legs and upper body) - thrombocytopenia (reduction in blood platelets which increases risks of bleeding and bruising

Side effects reported in children aged 2 years to 17 years

Frequency of side effects	**Side effects**
Very common: may affect more than 1 in 10 children	- injection-site pain and tenderness
Common: may affect up to 1 in 10 children	- headache - injection-site warmth, redness and swelling, fever, bleeding under the skin at the injection site (ecchymosis)
Uncommon: may affect up to 1 in 100 children	- irritability - dizziness - stomach ache, vomiting, diarrhoea, nausea - rash, itching - arm pain (in the injected limb), joint pain, muscle pain - weakness/tiredness, injection-site itching and pain/soreness
Rare: may affect up to 1 in 1,000 children	- loss of appetite - nervousness - sleepiness, abnormal skin sensations such as tingling - ear ache - flushing - runny or blocked nose, cough - hives, sweating - stiffness - hardness (induration) at the injection-site, flu-like illness, chest pain, pain, warmth, injection-site scab, stiffness/tightness and stinging

Not known: frequency cannot be estimated from the available data	- Guillain-Barré syndrome (muscle weakness, abnormal sensations, tingling in the arms, legs and upper body) - thrombocytopenia (reduction in blood platelets which increases risks of bleeding and bruising)

Reporting of side effects
If you or your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VAQTA 25 U/0.5 mL

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the label 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.

Do not use this vaccine if you notice that it has an unusual appearance (see section 6) or contains particulate matter.

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 protect the environment.

6. Contents of the pack and other information

What VAQTA 25 U/0.5 mL contains

The active ingredient is: Inactivated hepatitis A virus (produced on MRC-5 human diploid cells, adsorbed on amorphous aluminium hydroxyphosphate sulphate).

One dose (0.5 mL) contains 25 U hepatitis A virus (inactivated) adsorbed on amorphous aluminium hydroxyphosphate sulphate (0.225 milligram as aluminium).

The other ingredients are: Sodium borate, sodium chloride, and water for injections.

What VAQTA 25 U/0.5 mL looks like and contents of the pack

VAQTA 25 U/0.5 mL is a suspension for injection (0.5 mL in a pre-filled syringe)
- without needle – pack size of 1
- with one or two separate needle(s) – pack size of 1
- with attached needle – pack size of 1

Not all presentations and pack sizes may be marketed.

After thorough agitation VAQTA 25 U/0.5 mL is an opaque white suspension.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Merck Sharp & Dohme Ireland (Human Health) Limited,
Red Oak North, South County Business Park,
Leopardstown,
Dublin 18,
Ireland

Manufacturer:
Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	VAQTA K pro infantibus
Belgium, Luxembourg	VAQTA JUNIOR 25 U/0,5 ML
Portugal	VAQTA
Denmark, Finland, France	VAQTA 25 U/0,5 ml
Germany	VAQTA Kinder
Greece	VAQTA 25 U
Ireland	VAQTA PAEDIATRIC
Italy	VAQTA Bambini 25 U/0,5 ml, sospensione iniettabile in siringa preriempita
The Netherlands	VAQTA JUNIOR
Sweden	Vaqta
Spain	VAQTA 25 Unidades/0,5ml suspensión inyectable en jeringa precargada

This leaflet was last revised in September 2025.

The following information is intended for healthcare professionals only:

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Instructions for use and handling

The vaccine should be used as supplied.

The vaccine should be inspected visually prior to administration for any foreign particulate matter and/or abnormal physical appearance. Discard the product if particulates are present or if it appears discoloured. The syringe should be well shaken until a slightly opaque white suspension is obtained.

Thorough agitation is necessary to maintain suspension of the vaccine. For syringe without attached needle, hold the syringe barrel and attach the needle by twisting in clockwise direction until the needle fits securely on the syringe and give the vaccine immediately.