Package leaflet: Information for the user

VAQTA® 50 U/1 mL Suspension for injection in a prefilled syringe
Hepatitis A vaccine, inactivated, adsorbed
For adults

Read all of this leaflet carefully before you are 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 only. Do not pass it on to others.
- If you 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 50 U/1 mL is and what it is used for

VAQTA 50 U/1 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.

VAQTA50 U/1 mL helps to protect adults (18 years of age and older) 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 are given an injection of VAQTA 50 U/1 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 will be protected.

VAQTA 50 U/1 mL will not prevent hepatitis caused by infectious agents other than hepatitis A virus.

Additionally, if you are already infected with hepatitis A virus when you are given VAQTA 50 U/1 mL, the vaccination may not prevent the illness.

VAQTA 50 U/1 mL protects against hepatitis A but cannot cause a hepatitis A infection.

2. What you need to know before VAQTA 50 U/1 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 50 U/1 mL should not be given

- if you are allergic to the active substance, to any of the other ingredients of VAQTA 50 U/1 mL (listed in section 6) or to neomycin or formaldehyde (see section "Talk to your doctor, pharmacist or nurse before VAQTA 50 U/1 mL is given").

- if you currently have 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 50 U/1 mL is given

- if you have ever had an allergic reaction to a previous dose of VAQTA 50 U/1 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 have 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 have 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.

The container of this medicinal product contains latex rubber. Latex rubber may cause severe allergic reactions.

As with other vaccines, VAQTA 50 U/1 mL may not completely protect all persons who are vaccinated.

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

Other medicines and VAQTA 50 U/1 mL

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

Other vaccines

As VAQTA 50 U/1 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 50 U/1 mL must not be mixed with any other vaccine in the same syringe. Studies have demonstrated that VAQTA 50 U/1 mL may be given at the same time as yellow fever and polysaccharide typhoid vaccines.

Studies with a paediatric formulation have shown that the vaccine may be given at the same time as measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate, and inactivated polio vaccines.

Immunoglobulin (antibodies)

Sometimes, a human immunoglobulin (antibodies) injection will be given to try and protect you until the vaccine starts to work. VAQTA 50 U/1 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 may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice whether you should receive the vaccine.

Driving and using machines

There are no data to suggest that VAQTA 50 U/1 mL affects the ability to drive or operate machinery.

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

3. How VAQTA 50 U/1 mL is given

Dosage

VAQTA 50 U/1 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

Adults 18 years of age and older should receive an injection of a single 1.0 mL dose (50 U). The first dose of vaccine should protect you from infection with hepatitis A virus within 2 to 4 weeks.

Second (Booster) dose

Individuals having received the first dose of vaccine should receive the second (booster) dose of 1.0 mL (50 U) 6 to 18 months later.

Long term protection requires a second dose (booster dose) of the vaccine. Healthy adults who have had two doses have been found to have antibody levels for at least 6 years. It is predicted that hepatitis A antibodies will remain at least 25 years after vaccination.

Use in children and adolescents
VAQTA 50 U/1 mL is not recommended for individuals less than 18 years of age.

Method of administration

Your doctor or nurse will give you VAQTA 50 U/1 mL as an injection into a muscle in the upper part of the arm (deltoid muscle).
People who are at risk of bleeding a lot after an injection (e.g. haemophiliacs) may receive VAQTA 50 U/1 mL as an injection under the skin but not into the muscle to reduce the risk of bleeding.

VAQTA 50 U/1 mL must not be given into a blood vessel.

4. Possible side effects

Like all medicines and vaccines, this vaccine 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 are still in the clinic or doctor's surgery. **If any of these symptoms occurs after leaving the place where you received the injection, contact a doctor IMMEDIATELY.**

Frequency of side effects	**Side effects**
Very common: may affect more than 1 in 10 people	injection-site tenderness, pain, warmth, swelling, redness
Common: may affect up to 1 in 10 people	- headache - arm pain (in the injected arm) - weakness/tiredness, fever (38.3°C or over), bleeding under the skin at the injection site (ecchymosis), pain and soreness
Uncommon: may affect up to 1 in 100 people	- sore throat, upper respiratory infections - swelling of the lymph nodes - dizziness, abnormal skin sensations such as tingling - ear ache - hot flushes - runny or blocked nose and airways, cough - feeling sick (nausea), diarrhoea, excessive gas in the stomach and intestines, vomiting - hives, itching, redness - muscle pain, stiffness, shoulder pain, musculoskeletal pain (pain that affects the muscles, ligaments and tendons, along with the bones) back pain, joint pain, leg pain, neck pain, muscle weakness - itching at the injection-site, stiffness/tightness, pain, bruising at the injection-site, chills, stomach ache, feeling generally unwell, hardness (induration) and numbness at the injection-site, cold sensation, flu-like illness
Rare: may affect up to 1 in 1,000 people	- bronchitis, inflammation of the stomach and intestines (gastroenteritis) - loss of appetite - lacking energy, trouble sleeping - sleepiness, migraine, tremor - itching eyes, sensitivity to light, increased flow of tears - vertigo - swelling of the throat, problems with the sinuses - dryness of the mouth, mouth ulcers - night sweats, rash, skin disorders - muscle cramp, elbow pain, hip pain, jaw pain, spasm - problems with periods

	- injection-site burning, lump (≤2.5 centimetres), muscle twitching, rash, swelling of the stomach, chest pain, pain in the side; irritability -
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 get 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 50 U/1 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 50 U/1 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 (1 mL) contains 50 U hepatitis A virus (inactivated) adsorbed on amorphous aluminium hydroxyphosphate sulphate (0.45 milligram as aluminium).

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

What VAQTA 50 U/1 mL looks like and contents of the pack

VAQTA 50 U/1 mL is a suspension for injection (1 mL in a pre-filled syringe)
- without needle – pack size of 1 syringe.
- with one or two separate needle(s) – pack size of 1 syringe.
- with attached needle – pack size of 1 syringe.

Not all presentations and pack sizes may be marketed.

After thorough agitation VAQTA 50 U/1 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
Belgium, Luxembourg, Finland	VAQTA 50 U/1 ML
Germany, Portugal	VAQTA
Denmark	VAQTA (50 E/1ml)
France	VAQTA 50 U/1 ml
Greece	VAQTA 50 U
Ireland, The Netherlands	VAQTA Adult
Italy	VAQTA Adulti 50 U/1 ml, sospensione iniettabile in siringa preriempita
Sweden	Vaqta
Spain	VAQTA 50 Unidades/1ml suspensión inyectable en jeringa precargada

This leaflet was last revised in December 2021.

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.