Package Leaflet: Information for the User

VAQTA® Adult, Suspension for injection

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 Adult is and what it is used for.

Vaqta Adult is one of a general group of medicines called vaccines. Vaccines are used to protect against infectious diseases. They work by causing the body to produce its own protection against the targeted disease.

This vaccine helps to protect against hepatitis A infection.

Hepatitis A is a virus that attacks the liver, which can be caught from food or drink that contains the virus. Symptoms of hepatitis A include a yellowing of the skin and eyes (jaundice) and feeling generally unwell.

When an injection of this vaccine is given, the body's natural defences will produce protection (antibodies) against the hepatitis A infection. However, it usually takes 2 to 4 weeks after receiving the injection before you will be protected.

This vaccine will not protect you against other viruses that infect the liver (such as hepatitis B, hepatitis C or hepatitis E). This vaccine protects against hepatitis A but cannot cause hepatitis A infection.

The vaccination may not work properly if the person to be vaccinated is already infected with the hepatitis A virus.

Vaqta Adult is for adults aged 18 years and over. This vaccine is not suitable for anyone younger than 18 years of age.

2. What you need to know before VAQTA Adult is given

Do not use Vaqta Adult:

- if you are allergic to the active substance or any of the other ingredients of Vaqta Adult (listed in section 6) or to neomycin or formaldehyde (see section "Warnings and precautions").
- if you are ill with a high temperature. The vaccination should be delayed until you have recovered.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before Vaqta Adult is given:

- if you have ever had an allergic reaction to a previous dose of Vaqta Adult. 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 a poor or reduced immune system, due to:
  - corticosteroids, cytotoxic drugs or radiotherapy. Your doctor or nurse may wait until the treatment has finished.
  - HIV (human immunodeficiency virus infection) or any disease that affects the immune system. The vaccine may not protect as well as it protects people whose immune system is healthy.
- if you have any problems with the blood that causes easy bruising or bleeding for a long time after minor cuts. Your doctor or nurse may still advise that you should have Vaqta Adult but extra care is needed because of the risk of bleeding at the injection site. Your doctor or nurse may give Vaqta Adult as an injection under the skin instead of into muscle (see section 3) to try to reduce the risk of deep bleeding.

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

As with other vaccines, Vaqta Adult may not completely protect all persons who are vaccinated.

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

This vaccine can be given at the same time as any of the following provided that they are given in different parts of the body (for example another arm) and are not mixed in the same syringe.

- Vi polysaccharide typhoid vaccine,
- Yellow fever vaccine,
- Immunoglobulins (antibodies obtained from blood donors)

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, inactivated polio, diphtheria toxoid, tetanus toxoid, acellular pertussis or *Haemophilus influenzae* type b vaccines.

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 or using machines
There are no data to suggest that Vaqta Adult affects the ability to drive or operate machinery.

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

3. How VAQTA Adult is given

The vaccine will be injected by a doctor or nurse who has been trained in the use of vaccines and who is equipped to deal with any rare severe allergic reaction to the injection.

Short term protection against hepatitis A is achieved within 2 to 4 weeks after receiving this vaccination. This may take a little longer if the injection is given under the skin, rather than into the muscle.

Long-term protection against hepatitis A requires a second dose (booster injection) of an inactivated hepatitis A vaccine. This is usually given between 6 and 18 months after the first dose. This booster will protect you against hepatitis A for at least 6 years. It is predicted that hepatitis A antibodies will remain at least 25 years after vaccination.

If necessary, Vaqta Adult can be given as a booster injection 6 to 12 months after you received a first dose of another inactivated hepatitis A vaccine.

Method of administration
The doctor or nurse will shake the syringe immediately before use and check that the liquid is white and cloudy and that there are no large particles.

The vaccine is given as an injection into a muscle in the upper outer part of the arm. Your doctor or nurse will avoid giving you the injection either into the skin or into a blood vessel. People who are at risk of bleeding a lot after an injection (see section 2) may sometimes be given Vaqta Adult as an injection under the skin but not into muscle to try to reduce the risk of bleeding.

Use in children and adolescents
Vaqta Adult is not recommended for individuals less than 18 years of age.

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, 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 at 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 VAQTA Adult

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

The vaccine should not be used after the expiry date (Exp) which is stated on the carton and syringe or vial label.

The vaccine must be stored in a refrigerator between 2°C and 8°C (making sure that it does not freeze) so that the vaccine keeps its effectiveness.

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

One dose (1 mL) contains 50U hepatitis A virus (inactivated) adsorbed on amorphous aluminium hydroxyphosphate sulfate (0.45 milligram as aluminium).
The other ingredients are:

- sodium borate
- sodium chloride
- water for injections

What Vaqta Adult looks like and contents of the pack
A pre-filled syringe or vial containing 1 millilitre (one dose) of the vaccine.
The vaccine is available in single packs of the vial or pre-filled syringe with or without a needle.

Not all presentations may be marketed.

After thorough agitation Vaqta Adult is an opaque white suspension.

Marketing Authorisation Holder
The Marketing Authorisation Holder in the UK is:
Merck Sharp & Dohme (UK) Limited
120 Moorgate
London
EC2M 6UR
UK

Manufacturer
The manufacturer responsible for batch release at the following manufacturing sites is:
Merck Sharp and Dohme B.V.,
Waarderweg 39,
PO Box 581,
2003 PC Haarlem,
Netherlands

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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.

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