PACKAGE LEAFLET: INFORMATION FOR THE USER

VAQTA® Paediatric, Suspension for injection

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 gets 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 Paediatric is and what it is used for
2. What you need to know before Vaqta Paediatric is given
3. How Vaqta Paediatric is given
4. Possible side effects
5. How to store Vaqta Paediatric
6. Contents of the pack and other information

1. What VAQTA Paediatric is and what it is used for

Vaqta Paediatric 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 or your child will be protected.

This vaccine will not protect 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 a hepatitis A infection.

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

Vaqta Paediatric is for children from 12 months old up to 17 years old. This vaccine is not suitable for children under 12 months of age or adults aged 18 years and over.

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

Do not use Vaqta Paediatric:

- if you or your child is allergic to the active substance or any of the other ingredients of Vaqta Paediatric (listed in section 6) or to neomycin or formaldehyde (see section 'Warnings and precautions').
- if you or your child is ill with a high temperature. The vaccination should be delayed until you or your child has recovered.

Warnings and precautions

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

- if you or your child has ever had an allergic reaction to a previous dose of Vaqta Paediatric. 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 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 or your child has 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 or your child should have Vaqta Paediatric but extra care is needed because of the risk of bleeding at the injection site. Your doctor or nurse may give Vaqta Paediatric 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 Paediatric may not completely protect all persons who are vaccinated.

Please tell your doctor if you or your child have 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 Paediatric

Tell your doctor or pharmacist if you or your child is taking, has 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 or leg) and are not mixed in the same syringe.

- Measles, mumps, rubella and varicella (chickenpox) virus vaccines,

- Pneumococcal 7-valent conjugate vaccine,
- Polio vaccine (Inactivated),
- Diphtheria toxoid, tetanus toxoid, acellular pertussis, and *Haemophilus influenzae* b vaccines,
- Immunoglobulins (antibodies obtained from blood donors)

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

Pregnancy, breast-feeding and fertility
If you or your child is 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 Paediatric affects the ability to drive or operate machinery.

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

3. How VAQTA Paediatric 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.

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. 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.

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

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 (deltoid muscle). The muscle in the outer thigh region may be used in children if the deltoid muscle is not sufficiently developed. Your doctor or nurse will avoid giving you or your child the injection either into the skin or into a blood vessel. Children who are at risk of bleeding a lot after an injection (see section 2) may sometimes be given Vaqta

Paediatric as an injection under the skin but not into muscle to try to reduce the risk of bleeding.

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 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's injection was given, 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 - diarrhoea
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	- Guillain-Barré syndrome (muscle weakness, abnormal sensations, tingling in the arms, legs and upper body)

be estimated from the available data	- 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 Paediatric

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 Paediatric contains

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

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

The other ingredients are:
- sodium borate
- sodium chloride
- water for injections

What Vaqta Paediatric looks like and contents of the pack
A pre-filled syringe or vial containing 0.5 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 Paediatric 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

This leaflet was last revised in December 2020.

PIL.VAQ-P.20.UK.7356.MAT.RCN019044

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.

PIL.VAQ-P. 20.UK.7356.MAT.RCN019044