Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VAQTA®

Hepatitis A vaccine, purified inactivated

This patient medication information is written for the person who will be taking **VAQTA®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **VAQTA®**, talk to a healthcare professional.

What VAQTA® is used for:

- VAQTA® helps protect you or your child against hepatitis A disease, an infection of the liver caused by the hepatitis A virus. The vaccine can be administered to children 12 months of age and older, adolescents, and adults.

How VAQTA® works:

VAQTA® is a highly purified inactivated whole virus injectable vaccine that helps prevent infection of the liver caused by hepatitis A virus.

The ingredients in VAQTA® are:

Medicinal ingredient(s): Each 0.5 mL dose of the Pediatric/Adolescent formulation contains approximately 25 Units of hepatitis A virus antigen as the active ingredient. Each 1 mL dose of the Adult formulation contains approximately 50 Units of hepatitis A virus antigen as the active ingredient.

Non-medicinal ingredients: Aluminum provided as amorphous aluminum hydroxyphosphate sulfate, sodium borate and sodium chloride. The vaccine may contain trace amounts of neomycin.

The vial stopper contains latex.

VAQTA® comes in the following dosage form(s):

Pediatric/Adolescent Presentation - 0.5 mL single-use vials containing 25 U of hepatitis A virus antigen on an amorphous aluminum hydroxyphosphate sulfate adjuvant packaged in ones.

Adult Presentation - 1.0 mL single-use vials containing 50 U of hepatitis A virus protein on an amorphous aluminum hydroxyphosphate sulfate adjuvant, packaged in ones.

Do not use VAQTA® if:

- You are allergic to any component of the vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VAQTA®. Talk about any health conditions or problems you may have, including if you:

- You are allergic to any component of the vaccine.
- You are allergic to latex.

- You are pregnant or intend to become pregnant.
- You are breast-feeding.

Use in children
VAQTA® can be used in children and adolescents 12 months through 17 years of age.

Use in pregnancy
It is not known whether the vaccine is harmful to an unborn baby when administered to a pregnant woman. If you are pregnant, you should be vaccinated with VAQTA® only if your healthcare professional decides it is clearly needed.

Use in breast-feeding
Tell your healthcare professional if you are breast-feeding. If you are breast-feeding, you should be vaccinated with VAQTA® only if your healthcare professional decides it is clearly needed.

Can I drive or operate machinery after vaccination with VAQTA®?
There is no specific information on this; however, weakness/tiredness and headache have been reported following vaccination with VAQTA®.

Other warnings you should know about:

- 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.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may [also] interact with VAQTA®:

- VAQTA® may be given concomitantly with yellow fever, typhoid, measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate, oral or inactivated polio, diphtheria toxoid, tetanus toxoid, acellular pertussis, and Haemophilus influenzae b vaccines; however, data on concomitant use with other vaccines are limited. VAQTA® may also be given at the same time as immune globulin. Separate injection sites and syringes should be used for concomitant administration of injectable vaccines and immune globulin.

How to take VAQTA®:

- VAQTA® will be given to you by a healthcare professional in a healthcare setting.

Usual dose:

VAQTA® is given by injection. Two doses, each given on two different dates, are needed to complete the series. The schedule for children/adolescents and for adults is as follows:

Children and adolescents 12 months to 17 years of age should receive a 0.5 mL single dose (~25 Units) at any time and a 0.5 mL booster dose (~25 Units) 6 to 18 months later.

Adults 18 years of age and older should receive a 1.0 mL single dose (~50 Units) at any time and a

1.0 mL booster dose (~50 Units) 6 to 18 months later.

HIV-infected adults should receive a single 1.0 mL (~50 Units) dose of vaccine at elected date and a booster dose of 1.0 mL (~50 Units) 6 months later.

A booster dose of VAQTA® may be given at 6 to 12 months following the initial dose of other inactivated hepatitis A vaccines.

Overdose:

If you think you, or a person you are caring for, have taken too much VAQTA®, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose, your healthcare professional will decide when to give the missed dose.

Possible side effects from using VAQTA®:

These are not all the possible side effects you may have when taking VAQTA®. If you experience any side effects not listed here, tell your healthcare professional.

Any vaccine may have unintended or undesirable effects, so-called side effects. VAQTA® has been shown to be generally well tolerated. Side effects include:

- injection-site reactions such as soreness, redness, and swelling,
- generalized reactions including weakness/tiredness, fever, irritability, upper respiratory infection, nausea, abdominal pain, diarrhea, vomiting, sore throat, cold, headache and muscle pain.

Your healthcare professional has a more complete list of side effects.

Tell your healthcare professional promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

In addition, tell your healthcare professional if you or your child experienced any symptoms that suggest an allergic reaction (such as itching, hives, or rash) after any dose in the vaccination series.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting suspected side effects for vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada (PHAC), Health Canada (HC), and Merck Canada cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) and send it to your local Health Unit.

Storage:

Store vaccine refrigerated at 2°C to 8°C.

Do not freeze since freezing destroys potency.

Keep out of reach and sight of children.

If you want more information about VAQTA®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.merck.ca; or by calling 1-800-567-2594.

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