PART III: CONSUMER INFORMATION

VAQTA®
hepatitis A vaccine, purified inactivated

This leaflet is part III of a three-part "Product Monograph" published when VAQTA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VAQTA®. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine 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.

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

When it should not be used:
If you are allergic to any component of the vaccine.

What the medicinal ingredient is:
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.

What the important nonmedicinal ingredients are:
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.

What dosage forms it comes in:
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.

WARNINGS AND PRECAUTIONS

BEFORE you use VAQTA® talk to your doctor or pharmacist if:

- 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 doctor decides it is clearly needed.

Use in breast-feeding
Tell your doctor if you are breast-feeding. If you are breast-feeding, you should be vaccinated with VAQTA® only if your doctor 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 considerations
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.

INTERACTIONS WITH THIS VACCINE

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.

PROPER USE OF THIS VACCINE

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:

In case of overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you miss a dose, your doctor will decide when to give the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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, and generalized reactions including weakness/tiredness, fever, irritability, upper respiratory infection, nausea, abdominal pain, diarrhea, vomiting, sore throat, cold, headache and muscle pain.

Your doctor has a more complete list of side effects.

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

In addition, tell your doctor 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.

This is not a complete list of side effects. For any unexpected effects, contact your doctor or pharmacist.

HOW TO STORE IT

Store vaccine refrigerated at 2°C to 8°C (36°F - 46°F).

Do not freeze since freezing destroys potency.

Reporting Suspected Vaccine Adverse Events

For the general public:
If you suspect you have had a serious or unexpected event following receipt of a vaccine, please ask your healthcare professional to complete the Adverse Events Following Immunization (AEFI) Form and send it to your local health unit in your province/territory.

For healthcare professionals:
If a patient experiences an adverse event following immunization, please complete the Adverse Events Following Immunization (AEFI) Form and send it to your local health unit in your province/territory.

If you have any questions or have difficulty contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

Toll-free telephone: 1-866-844-0018
Toll-free fax: 1-866-844-5931
By email: caefi@phac-aspc.gc.ca

NOTE: Should you require information related to the management of the adverse events, please contact your health professional before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

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 this Consumer Information by visiting the Health Canada website or Merck Canada web site www.merck.ca or by calling Merck Canada at 1-800-567-2594

To report an adverse event related to VAQTA®, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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