

## PART III: CONSUMER INFORMATION

# VAQTA<sup>®</sup>

hepatitis A vaccine, purified inactivated

This leaflet is part III of a three-part "Product Monograph" published when VAQTA<sup>®</sup> 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<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the vaccine.

### ABOUT THIS VACCINE

#### What the vaccine is used for:

VAQTA<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> only if your doctor decides it is clearly needed.

#### **Can I drive or operate machinery after vaccination with VAQTA<sup>®</sup>?**

There is no specific information on this; however, weakness/tiredness and headache have been reported following vaccination with VAQTA<sup>®</sup>.

#### **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<sup>®</sup> may be given concomitantly with yellow fever, typhoid, measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate and oral or inactivated polio vaccines; however, data on concomitant use with other vaccines are limited. VAQTA<sup>®</sup> 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<sup>®</sup> 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 months later.

A booster dose of VAQTA<sup>®</sup> 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<sup>®</sup> 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 SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect you have had a serious or unexpected event following receipt of a vaccine you may notify the Public Health Agency of Canada:

By toll-free telephone: 1-866-844-0018

By toll-free fax: 1-866-844-5931

By e-mail: CAEFI@phac-aspc.gc.ca

By regular mail:

The Public Health Agency of Canada  
Vaccine Safety Section  
130 Colonnade Road  
Ottawa, ON K1A 0K9  
A/L 6502A

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-496-9092, or
  - Mail to: Merck Canada Inc.  
Pharmacovigilance  
P.O. Box 1005  
Pointe-Claire - Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of the side effects, contact your health professional. The Public Health Agency of Canada or Merck do not provide medical advice.

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.merck.ca>

or by contacting the sponsor, Merck Canada Inc., at: 1-800-567-2594

This leaflet was prepared by Merck Canada Inc.

Last revised: April 29, 2011

® Registered trademarks of Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.** Used under license.

\* All other trademarks are the property of their respective owners.

© 2011, Merck Canada Inc., a subsidiary of **Merck & Co., Inc.** All rights reserved.

