Product Monograph

Including Patient Medication Information

VAQTA®

hepatitis A vaccine, purified inactivated

25 U of hepatitis A virus protein/0.5 mL dose (pediatric/adolescent presentation)

50 U of hepatitis A virus protein/1.0 mL dose (adult presentation)

Suspension for injection, intramuscular

Active Immunizing Agent against hepatitis A virus

ATC Code: J07BC02

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Date of Authorization:
September 28, 2026

Control Number: 500987

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Part 1: Healthcare professional information

1. Indications

VAQTA® hepatitis A vaccine, purified inactivated is indicated for:

- vaccination against infection caused by hepatitis A virus
- active pre-exposure prophylaxis against disease caused by hepatitis A virus. Vaccination is recommended for individuals 12 months of age and older.

Please refer to the National Advisory Committee on Immunization (NACI) and the Canadian Immunization Guide for recommendations of use.

Revaccination: See 4. Dosage and Administration.

1.1. Pediatrics

Pediatrics (12 months to 17 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of VAQTA® in pediatric patients has been established. Therefore, Health Canada has authorized an indication for pediatric use (See 4. Dosage and Administration).

Pediatrics (< 12 months of age): Safety and effectiveness in infants below 12 months of age have not been established.

1.2. Geriatrics

Geriatrics (> 65 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

2. Contraindications

VAQTA® hepatitis A vaccine, purified inactivated should not be administered to:

Patients who are hypersensitive to this vaccine or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing see 6. Dosage Forms, Strengths, Composition, And Packaging.

4. Dosage and administration

4.1. Dosing Considerations

- **For intramuscular use only.** For adults, adolescents, and children older than 2 years of age, the deltoid muscle is the preferred site for intramuscular injection. For children 12 through 23 months of age, the anterolateral area of the thigh is the preferred site for intramuscular injection.
- Do not inject intravascularly, intradermally, or subcutaneously

4.2. Recommended Dose and Dosage Adjustment

The vaccination series consists of one primary dose and one booster dose given according to the following schedule:

- **Children/Adolescents - 12 Months Through 17 Years of Age:** Individuals 12 months through 17 years of age should receive a single 0.5 mL (~25 U) dose of vaccine at an elected date and a booster dose of 0.5 mL (~25 U) 6 to 18 months later.

- **Adults:** Adults 18 years of age and older should receive a single 1.0 mL (~50 U) dose of vaccine at an elected date and a booster dose of 1.0 mL (~50 U) 6 to 18 months later.

- **Adults With Human Immunodeficiency Virus (HIV):** HIV-infected adults should receive a single 1.0 mL (~50U) dose of vaccine at elected date and a booster dose of 1.0 mL (~50U) 6 months later.

- **Interchangeability of the Booster Dose:** A booster dose of VAQTA® may be given at 6 to 12 months following the initial dose of other inactivated hepatitis A vaccines.

4.4. Administration

Use With Other Vaccines: Separate injection sites and syringes should be used for concomitant administration of injectable vaccines (see 9.4 Drug-drug interactions).

Known or Presumed Exposure to Hepatitis A Virus, Travel to Endemic Areas, and Use With Immune Globulin

VAQTA® may be administered concomitantly with IG using separate sites and syringes. The vaccination regimen for VAQTA® should be followed as stated above. Consult the manufacturers' Product Monograph for the appropriate dosage of IG. A booster dose of VAQTA® should be administered at the appropriate time as outlined above (see 14. Clinical Trials and 9. Drug-Drug Interactions).

The vaccine should be used as supplied; no reconstitution is necessary.

Shake well before withdrawal and use. Thorough agitation is necessary to maintain suspension of the vaccine.

Parenteral drug products should be inspected visually for extraneous particulate matter and discoloration prior to administration whenever solution and container permit. After thorough agitation, VAQTA® is a slightly opaque, white suspension.

It is important to use a separate, sterile syringe and needle for each individual to prevent transmission of infectious agents from one person to another.

4.5. Missed Dose

If a dose is missed, the physician will decide when to give it.

5. Overdose

For the most recent information in the management of a suspected vaccine overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, healthcare professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number, and expiry date.

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
Intramuscular Injection	Suspension for injection 25 U of hepatitis A virus protein/0.5 mL dose (pediatric/adolescent presentation)	Aluminum (as amorphous aluminum hydroxyphosphate sulfate), Sodium borate, Sodium chloride, water for injection
Intramuscular Injection	Suspension for injection 50 U of hepatitis A virus protein/1.0 mL dose (adult presentation)	Aluminum (as amorphous aluminum hydroxyphosphate sulfate), Sodium borate, Sodium chloride, water for injection

Description

VAQTA® (hepatitis A vaccine, purified inactivated) is supplied as a sterile, slightly opaque, white suspension for injection in a single-dose vial.

The vaccine should be used as supplied; no reconstitution is necessary.

Manufacturing Process Residuals

Within the limits of current assay variability, the 50 unit (1 mL) dose of VAQTA® contains less than 0.1 µg (less than 100 ng) of non-viral protein, less than 4 x 10^{-6} µg (less than 0.004 ng) of DNA, less than 10^{-4} µg (less than 0.1 ng) of bovine albumin, less than 0.8 µg (less than 800 ng) of formaldehyde and a trace of neomycin [≤ 0.002 µg (≤ 2 ng)]. Other process chemical residuals are less than 10 parts per billion (ppb). VAQTA® meets the World Health Organization requirement for biological substances including those for final vaccine residual bovine serum albumin.

Pediatric/Adolescent Presentation: VAQTA® is supplied in 3 mL, single-dose Type 1 glass vials containing one 0.5 mL dose (25 U of hepatitis A virus protein). The vial stopper contains latex. VAQTA® is available in packages of 1 single-dose vial.

Adult Presentation: VAQTA® is supplied in 3 mL, single-dose Type 1 glass vials containing one 1.0 mL dose (50 U of hepatitis A virus protein). The vial stopper contains latex. VAQTA® is available in packages of 1 single-dose vial.

7. Warnings and Precautions

If VAQTA® is used in individuals with malignancies or those receiving immunosuppressive therapy or who are otherwise immunocompromised, the expected immune response may not be obtained.

VAQTA® is not recommended for use in infants younger than 12 months of age since data on use in this age group are not currently available.

General

Individuals who develop symptoms suggestive of hypersensitivity after an injection of VAQTA® should not receive further injections of the vaccine (see 2. Contraindications).

As with any vaccine, adequate treatment provisions, including epinephrine, should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

Since there is a possibility that the vaccine may contain trace amounts of neomycin, the possibility of an allergic reaction in individuals sensitive to this substance should be kept in mind when considering the use of this vaccine (see 6. Dosage Forms, Strengths, Composition, And Packaging).

The vial stopper contains dry natural latex rubber. If a person reports a severe (anaphylactic) allergy to latex, products supplied in vials or syringes that contain natural rubber should not be administered, unless the benefit of administration outweighs the risk of an allergic reaction resulting from administration of the vaccine. A history of contact dermatitis to dry natural latex rubber is not a contraindication to receiving this vaccine.

VAQTA® may be administered subcutaneously when clinically appropriate (e.g., people with bleeding disorders who are at risk of hemorrhage), although the kinetics of seroconversion are slower for the first subcutaneous dose of VAQTA® compared with historical data for intramuscular administration.

As with any vaccine, vaccination with VAQTA® may not result in a protective response in all susceptible vaccinees.

Any acute infection or febrile illness may be reason for delaying use of VAQTA® except when, in the opinion of the physician, withholding the vaccine entails a greater risk.

VAQTA® will not prevent hepatitis caused by infectious agents other than hepatitis A virus. Because of the long incubation period (approximately 20 to 50 days) for hepatitis A, it is possible for unrecognized hepatitis A infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis A in such individuals.

7.1. Special Populations

7.1.1. Pregnancy

Animal reproduction studies have not been conducted with VAQTA®. It is also not known whether VAQTA® can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. VAQTA® should be given to a pregnant woman only if clearly needed.

7.1.2. Breastfeeding

It is not known whether VAQTA® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VAQTA® is administered to a woman who is breast feeding.

7.1.3. Pediatrics

Pediatrics (12 months to 17 years of age): VAQTA® has been shown to be generally well-tolerated and highly immunogenic in individuals 12 months through 17 years of age, see 4.2. Recommended Dose and Dosage Adjustment for the recommended dosage schedule.

Pediatrics (< 12 month): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use in infants below 12 months of age. Safety and effectiveness in infants below 12 months of age have not been established.

VAQTA® is not recommended for use in infants younger than 12 months of age since data on use in this age group are not currently available.

8. Adverse Reactions

8.2. Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies reported in clinical trials of another drug.

Adults - 18 Years of Age and Older

In combined clinical trials involving 1529 healthy adults who received one or more ~50 U doses of hepatitis A vaccine, subjects were followed for fever and local complaints during a 5-day period postvaccination and systemic complaints during a 14-day period postvaccination. Injection-site complaints, generally mild and transient, were the most frequently reported complaints. Table 2 lists the complaints reported by ≥ 1% of subjects, without regard to causality, in decreasing order of frequency within each body system.

Table 2 - Local and Systemic Complaints (≥ 1%) in Healthy Adults from Combined Clinical Trials

Localized Injection-Site Reactions (generally mild and transient)	
Tenderness	52.6%
Pain	51.1%
Warmth	17.3%
Swelling	13.6%
Erythema	12.9%
Ecchymosis	1.5%
Pain/soreness	1.2%
Body as a Whole	
Asthenia/fatigue	3.9%
Fever ≥ 38.3°C, Oral	2.6%
Abdominal pain	1.3%
Digestive System	
Diarrhea	2.4%
Nausea	2.3%
Musculoskeletal System	
Myalgia	2.0%
Arm pain	1.3%
Back pain	1.1%
Stiffness	1.0%
Nervous System/Psychiatric	
Headache	16.1%
Respiratory System	
Upper respiratory infection	2.8%
Pharyngitis	2.7%
Nasal congestion	1.1%
Urogenital System	
Menstruation disorder	1.1%

Local and/or systemic hypersensitivity reactions occurred in <1% of children, adolescents, or adults in clinical trials and included the following regardless of causality: pruritus, urticaria, and rash.

As with any vaccine, there is the possibility that use of VAQTA® in very large populations might reveal adverse experiences not observed in clinical trials.

8.2.1. Clinical Trial Adverse Reactions – Pediatrics

Children – 12 Months Through 23 Months of Age

In 5 combined clinical trials (Protocols 043, 057, 066, 067, and 068), 4374 children 12 through 23 months of age received one or two ~25U doses of VAQTA®. Out of the 4374 children who received VAQTA®, 3885 (88.8%) children received 2 doses of VAQTA®, with 1250 (32.2%) of those children receiving VAQTA® concomitantly with other vaccines. Children were followed for elevated temperature and injection-site adverse reactions during a 5-day period postvaccination and systemic adverse events during a 14-day period postvaccination.

The most frequently reported injection-site adverse reaction after any dose of VAQTA® was injection-site pain/tenderness/soreness. The data from three of the five protocols (066, 067, and 068) were combined as these three studies specifically prompted for injection-site erythema, pain/tenderness/soreness, and swelling daily for Day 1 through Day 5 postvaccination whereas Protocols 043 and 057 did not.

The most common systemic adverse events among recipients of VAQTA® alone and VAQTA® given concomitantly with other vaccines were pyrexia (fever >37.0oC or feverish) and irritability. The rates of all other systemic adverse events were comparable between recipients of VAQTA® alone and VAQTA® given concomitantly with other vaccines. The data from the five protocols were combined as similar methods for collecting systemic adverse events were used.

The adverse events that were observed among recipients of VAQTA® alone or VAQTA® given concomitantly with measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate, oral or inactivated polio, diphtheria toxoid, tetanus toxoid, acellular pertussis, and *Haemophilus influenzae* b vaccines at a frequency of at least 1.0% and regardless of causality, are listed in decreasing order of frequency within each system organ class.

Table 3 - Adverse Events in Children 12 Months Through 23 Months of Age Administered VAQTA® Alone and VAQTA® Given Concomitantly with Measles, Mumps, Rubella, Varicella, Pneumococcal 7-valent Conjugate, Oral or Inactivated Polio, Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis, or *Haemophilus Influenzae* b Vaccines

Adverse Event	VAQTA® Alone (at both doses)	VAQTA® Given Concomitantly (at least one dose)
Infections and infestations		
Upper respiratory infection	7.4%	8.9%
Otitis media	4.6%	6.4%
Nasopharyngitis	3.6%	3.4%
Rhinitis	2.2%	1.4%
Viral infection	1.1%	1.6%
Croup	1.0%	0.7%
Gastroenteritis	1.0%	0.7%
Otitis	0.8%	1.5%
Laryngotracheobronchitis	0.2%	1.1%
Metabolism and nutrition disorders		
Decreased appetite	0.7%	1.1%
Nervous system disorders		
Crying	0.4%	1.1%
Eye disorders		
Conjunctivitis	1.0%	1.3%
Respiratory, thoracic, and mediastinal disorders		
Rhinorrhea	6.8%	6.4%
Cough	6.5%	5.5%
Nasal congestion	2.3%	2.2%
Respiratory congestion	0.4%	1.0%
Gastrointestinal disorders		
Diarrhea	8.0%	7.2%
Vomiting	5.0%	4.3%
Teething	2.4%	0.6%

Adverse Event	VAQTA® Alone (at both doses)	VAQTA® Given Concomitantly (at least one dose)
Skin and subcutaneous tissue disorders		
Dermatitis diaper	1.9%	4.0%
Rash	1.8%	4.7%
Measles-like/rubella-like rash	0.0%	2.2%
General disorders and administration site conditions		
Injection-site pain/tenderness/soreness	37.4%	36.0%
Injection-site erythema	21.5%	20.4%
Pyrexia (fever >37.0°C or feverish, Days 1-14)	16.4%	27.0%
Injection-site swelling	12.7%	14.6%
Irritability	10.4%	11.1%
Fever ≥39.0°C, Oral (Days 1-5)	4.2%	4.8%
Injection-site bruising	1.7%	1.7%
Injection-site hematoma	1.0%	0.8%

Children/Adolescents - 2 through 17 Years of Age

In combined clinical trials involving 2595 healthy children (≥ 2 years of age) and adolescents who received one or more ~25 U doses of hepatitis A vaccine, subjects were followed for fever and local complaints during a 5-day period postvaccination and systemic complaints during a 14-day period postvaccination. Injection-site complaints, generally mild and transient, were the most frequently reported complaints. Table 4 lists the complaints reported by ≥ 1% of subjects, without regard to causality, in decreasing order of frequency within each body system.

Table 4 - Local and Systemic Complaints (≥ 1%) in Healthy Children and Adolescents from Combined Clinical Trials

Localized Injection-Site Reactions (generally mild and transient)	
Pain	18.7%
Tenderness	16.8%
Warmth	8.6%
Erythema	7.5%
Swelling	7.3%
Ecchymosis	1.3%
Body as a Whole	
Fever ≥ 38.9°C, Oral	3.1%
Abdominal pain	1.6%
Digestive System	
Diarrhea	1.0%
Vomiting	1.0%
Nervous System/Psychiatric	
Headache	2.3%
Respiratory System	
Pharyngitis	1.5%
Upper respiratory infection	1.1%
Cough	1.0%

8.4. Abnormal Laboratory Findings: Hematologic, Clinical Chemistry, and Other Quantitative Data

Clinical Trial Findings

Very few laboratory abnormalities were reported and included isolated reports of elevated liver function tests, eosinophilia, and increased urine protein.

In The Monroe Efficacy Study, 1037 healthy children and adolescents 2 to 16 years of age received either a primary dose of ~ 25 U of hepatitis A vaccine and a booster 6, 12, or 18 months later, or placebo. Subjects were observed during a 5-day period for fever and local complaints and during a 14-day period for systemic complaints. Injection-site complaints, generally mild and transient, were the most frequently reported complaints. Table 5 summarizes the local and systemic complaints (≥ 1%) reported in this study, without regard to causality. There were no significant differences in the rates of any complaint between vaccine and placebo recipients after Dose 1.

Table 5 - Local and Systemic Complaints (≥ 1%) in Healthy Children and Adolescents From the Monroe Efficacy Study

REACTION	VAQTA®		Placebo†
	Dose 1*	Booster	
Injection-Site Complaints			
Pain	6.4% (33/515)	3.4% (16/475)	6.3% (32/510)
Tenderness	4.9% (25/515)	1.7% (8/475)	6.1% (31/510)
Erythema	1.9% (10/515)	0.8% (4/475)	1.8% (9/510)
Swelling	1.7% (9/515)	1.5% (7/475)	1.6% (8/510)
Warmth	1.7% (9/515)	0.6% (3/475)	1.6% (8/510)
Systemic Complaints			
Abdominal Pain	1.2% (6/519)	1.1% (5/475)	1.0% (5/518)
Pharyngitis	1.2% (6/519)	0% (0/475)	0.8% (4/518)
Headache	0.4% (2/519)	0.8% (4/475)	1.0% (5/518)

* No statistically significant differences between the two groups.
† Second injection of placebo not administered because code for the trial was broken.

8.5. Post-Market Adverse Reactions

Post-marketing Safety Study

In a post-marketing safety study, a total of 42,110 individuals ≥ 2 years of age received 1 or 2 doses of VAQTA®. There was no serious, vaccine-related, adverse event identified. There was no nonserious, vaccine-related, adverse event resulting in outpatient visits, with the exception of diarrhea/gastroenteritis in adults at a rate of 0.5%.

Marketed Experience

The following additional adverse reactions have been reported with use of the marketed vaccine:

Nervous System: Very rarely, Guillain-Barré syndrome, cerebellar ataxia, encephalitis.

Hemic and Lymphatic system: Very rarely, thrombocytopenia.

9. Drug Interactions

9.3. Drug-Behaviour Interactions

The interaction of VAQTA® with individual behavioural risks has not been studied.

9.4. Drug-Drug Interactions

Use With Other Vaccines
VAQTA® may be given concomitantly with measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate, oral or inactivated polio, diphtheria toxoid, tetanus toxoid, acellular pertussis, and Haemophilus influenzae b vaccines.

Adults – 18 Years of Age and Older
VAQTA® may be given concomitantly with yellow fever and typhoid vaccines.

Data on concomitant use with other vaccines are limited (see 4. Dosage and Administration).

Separate injection sites and syringes should be used for concomitant administration of injectable vaccines.

Vaccines administered simultaneously should be given using separate syringes at separate sites (unless otherwise specified by the manufacturer), consideration being given to the precautions that apply to each individual vaccine. Concomitant administration of other vaccines at other injection sites is unlikely to interfere with the immune response to hepatitis A vaccine.

The Advisory Committee on Immunization Practices has stated that limited data from studies conducted among adults indicate that simultaneous administration of hepatitis A vaccine with diphtheria, poliovirus (oral and inactivated), tetanus, oral typhoid, cholera, Japanese encephalitis, rabies, or yellow fever vaccine does not decrease the immune response to either vaccine or increase the frequency of reported adverse events. Studies indicate that hepatitis B vaccine can be administered with VAQTA® without affecting immunogenicity or increasing the frequency of adverse events.

Use with Immune Globulin
For individuals requiring either post exposure prophylaxis or combined immediate and longer-term protection (e.g., travelers departing on short notice to endemic areas), VAQTA® may be administered concomitantly with immune globulin (IG) using separate sites and syringes.

9.5. Drug-Food Interactions

Interactions with food have not been established.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1. Mechanism of Action

VAQTA® is an inactivated whole virus vaccine which has been shown to induce antibody to hepatitis A virus protein.

Disease Epidemiology

Hepatitis A virus is one of several hepatitis viruses that cause a systemic infection with pathology in the liver. The incubation period ranges from approximately 20 to 50 days. While the course of the disease is generally benign and does not result in chronic hepatitis, infection with hepatitis A virus remains an important cause of morbidity and occasional fulminant hepatitis and death.

Hepatitis A is transmitted most often by the fecal-oral route, with infection occurring within private households, day-care centers, neonatal intensive care units, and chronic-care hospitals. Common-source outbreaks due to contaminated food and water supplies have occurred following consumption of certain foods such as raw shellfish, and uncooked foods prepared by an infected food-handler or otherwise contaminated prior to ingestion (salads, sandwiches, frozen raspberries, etc). Bloodborne transmission, while uncommon, is possible via blood transfusion, contaminated blood products, or from needles shared with an infected viremic individual. Sexual transmission has also been reported.

The disease burden due to hepatitis A as of 2006 in the United States has been estimated to be approximately 3579 cases of clinical hepatitis each year, resulting in 549 hospitalizations, and 5 deaths due to fulminant hepatitis. Worldwide, it has been estimated that 1.4 million cases occur annually.2 The clinical manifestations of hepatitis A infection often pass unrecognized in children < 6 years of age whereas overt hepatitis develops in the majority of infected older children and adults. Symptoms and signs of hepatitis A infection are similar to those associated with other types of viral hepatitis and include anorexia, nausea, fever/chills, jaundice, dark urine, light-colored stools, abdominal pain, malaise, and fatigue.

11. Storage, Stability, and Disposal

Store vaccine refrigerated at 2°C to 8°C. **Do not freeze (below 0°C) since freezing destroys potency.**

VAQTA® can be administered provided total (cumulative multiple excursion) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 72 hours. Cumulative multiple excursions between 0°C and 2°C are also permitted, as long as the total time between 0°C and 2°C does not exceed 72 hours. These are not, however, recommendations for storage.

Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Non-proprietary name of the drug substance: hepatitis A vaccine, purified inactivated.

Product Characteristics:

VAQTA® is a sterile suspension for intramuscular injection. It is a highly purified inactivated whole virus vaccine derived from hepatitis A virus grown in cell culture in human MRC-5 diploid fibroblasts. It contains inactivated virus of a strain which was originally derived by further serial passage of a proven attenuated strain. The virus is grown, harvested, purified by a combination of physical and high performance liquid chromatographic techniques, formalin inactivated, and then adsorbed onto amorphous aluminum hydroxyphosphate sulfate. One milliliter of the vaccine contains approximately 50 units (U) of hepatitis A antigen, equivalent to approximately 50 nanograms (ng) of virus protein per mL which is highly purified and is formulated without a preservative.

14. Clinical Trials

14.1. Clinical Trials by Indication

Clinical Evaluation

Clinical trials conducted worldwide with several formulations of the vaccine in 4374 children 12 through 23 months of age and 9421 healthy individuals ranging from 2 to 85 years of age have demonstrated that VAQTA® (hepatitis A vaccine, purified inactivated) is highly immunogenic and generally well tolerated.

Protection from hepatitis A disease has been shown to be related to the presence of antibody; an anamnestic antibody response occurs in healthy individuals with a history of infection who are subsequently re-exposed to hepatitis A virus. Protection after vaccination with VAQTA® was associated with the onset of seroconversion (≥ 10 mIU/mL of hepatitis A antibody) and with an anamnestic antibody response following booster vaccination with VAQTA®.

In a post-marketing safety study, conducted at a large health maintenance organization in the United States, a total of 42,110 individuals ≥ 2 years of age received 1 or 2 doses of VAQTA®. Safety was monitored by reviewing medical records that tracked emergency room and outpatient visits, hospitalizations and deaths. There was no serious, vaccine-related, adverse event identified among the 42,110 individuals in this study. There was no nonserious, vaccine-related, adverse event resulting in outpatient visits, with the exception of diarrhea/gastroenteritis in adults at a rate of 0.5%. There was no vaccine-related, adverse event identified that had not been reported in earlier clinical trials with VAQTA®.

Immunogenicity

Children – 12 Months Through 23 Months of Age

In Protocol 057, an open, multicenter clinical study, children ~12 months of age were randomized to receive the first and second doses of VAQTA® with or without other vaccines. 96% of 471 children were seropositive (defined as having a titer ≥ 10 mIU/mL) within 6 weeks after the primary ~25 U intramuscular dose of VAQTA®. The observed hepatitis A seroresponse rate 4 weeks postdose 2 when

VAQTA® was administered with or without other vaccines was 100%. After each dose of VAQTA®, the hepatitis A antibody titers were comparable between children who were initially seropositive to hepatitis A and children who were initially seronegative to hepatitis A. These data suggest that maternal antibody to hepatitis A in children ~12 months of age does not affect the immune response to VAQTA®.

In Protocol 067, an open label clinical study, 653 children 12 through 23 months of age, were randomized to receive two ~25 U intramuscular doses of VAQTA® 6 months apart with or without other vaccines, 100% (n=182; 95% CI: 98.0%, 100%) were seropositive within 4 weeks after the second dose of VAQTA® given with other vaccines for both doses, and 99.4% (n=159, 95% CI: 96.5%, 100%) were seropositive within 4 weeks after 2 doses of VAQTA® only.

In Protocol 068, an open, multicenter, comparative study, 617 children 15 months of age were randomized to receive VAQTA® with or without other vaccines. The observed hepatitis A seroresponse rate (percent with titer ≥ 10 mIU/mL) taken 4 weeks postdose 2 was 100% (n=208, 95% CI: 98.2%, 100.0%) in those who received VAQTA® concomitantly and 100% (n=183, 95% CI: 98.0%, 100.0%) in those subjects who received VAQTA® alone.

In three combined clinical studies (Protocols 057, 067 and 068), 1022 initially seronegative subjects received 2 doses of VAQTA® alone or concomitantly with other vaccines. Of the seronegative subjects, 99.9% achieved a titer ≥ 10 mIU/mL (95% CI: 99.5%, 100%).

Children/Adolescents – 2 Through 17 Years of Age
In combined clinical studies, 97% of 1214 children and adolescents 2 to 17 years of age seroconverted within 4 weeks after a single ~25 U intramuscular dose of VAQTA®. Similarly, 95% of 1428 adults ≥ 18 years of age seroconverted within 4 weeks after a single ~50 U intramuscular dose of VAQTA®. Immune memory was later demonstrated by an anamnestic antibody response in individuals who received a booster dose (see 14.1. Clinical Trials by Indication, Persistence).

While a study evaluating VAQTA® alone in a post-exposure setting has not been conducted, the concurrent use of VAQTA® (~50 U) and immune globulin (IG, 0.06 mL/kg) was evaluated in a clinical study involving healthy adults 18 to 39 years of age. Table 6 provides seroconversion rates at 4 and 24 weeks after the first dose in each treatment group and at one month after a booster dose of VAQTA® (administered at 24 weeks).

Table 6 - Seroconversion Rates After Vaccination With VAQTA® Plus IG, VAQTA® Alone, and IG Alone

	VAQTA® plus IG	VAQTA®	IG
Weeks	**Seroconversion Rate†**		
4	100% (n=129)	96% (n=135)	87% (n=30)
24	92% (n=125)	†97% (n=132)	0% (n=28)
28	100% (n=114)	100% (n=128)	N/A

† Seroconversion rate in the vaccine alone group significantly higher than that in the vaccine plus IG group (p=0.05).
N/A= Not Applicable.

A very high degree of protection has been demonstrated after a single dose of VAQTA® in children and adolescents.[7] The protective efficacy, immunogenicity, and safety of VAQTA® were evaluated in a randomized, double-blind, placebo-controlled study involving 1037 susceptible healthy children and adolescents 2 to 16 years of age in a U.S. community with recurrent outbreaks of hepatitis A (The Monroe Efficacy Study). Each child received a single intramuscular dose of VAQTA® (~25 U) or placebo. Among those individuals who were initially seronegative (measured by a modification of the HAVAB* radioimmunoassay [RIA]), seroconversion was achieved in > 99% of vaccine recipients within 4 weeks after vaccination. The onset of seroconversion following a single dose of VAQTA® was shown to parallel the onset of protection against clinical hepatitis A disease.

Because of the long incubation period of the disease (approximately 20 to 50 days or longer in children), analysis of protective efficacy was based on cases of hepatitis A occurring ≥ 50 days after vaccination in order to exclude any children incubating the infection before vaccination. In subjects who were initially seronegative, the protective efficacy of a single dose of VAQTA® was observed to be 100% with 21 cases of clinical hepatitis A occurring in the placebo group and none in the vaccine group ($p<0.001$). No cases of clinical hepatitis A disease occurred in the vaccine group after day 16. In addition, 28 cases of clinical hepatitis A occurred in the placebo group while none occurred in the vaccine group ≥ 30 days after vaccination. Following demonstration of protection with a single dose and termination of the study, a booster dose was administered to most vaccinees 6, 12, or 18 months after the primary dose. The effectiveness of VAQTA® for use in community outbreak control has been demonstrated by the fact that, to date, no cases of hepatitis A disease ≥ 19 days after vaccination have occurred in those vaccinees from The Monroe Efficacy Study monitored for up to 9 years. In contrast, three nearby sister communities to Monroe have continued to experience outbreaks.

Persistence

The total duration of the protective effect of VAQTA® in healthy vaccinees is unknown at present. However, seropositivity was shown to persist up to 18 months after a single ~ 25 U dose in most children and adolescents who participated in The Monroe Efficacy Study. In adults, seropositivity has been shown to persist up to 18 months after a single ~ 50 U dose.

Persistence of immunologic memory was demonstrated with an anamnestic antibody response to a booster dose of ~ 25 U given 6 to 18 months after the primary dose in children and adolescents, and to a booster dose of ~ 50 U given 6 to 18 months after the primary dose to adults.

In studies of healthy children (≥ 2 years of age) and adolescents who received two doses (~ 25 U) of VAQTA® at 0 and 6 to 18 months, detectable levels of anti-HAV antibodies (≥ 10 mIU/mL) were present in 100% of subjects available for testing for at least 10 years postvaccination. In subjects who received VAQTA® at 0 and 6 months, the GMT was 819 mIU/mL (n=175) at 2.5 to 3.5 years and 505 mIU/mL (n=174) at 5 to 6 years, and 574 mIU/mL (n=114) at 10 years postvaccination. In subjects who received VAQTA® at 0 and 12 months, the GMT was 2224 mIU/mL (n=49) at 2.5 to 3.5 years, 1191 mIU/mL (n=47) at 5 to 6 years, and 1005 mIU/mL (n=36) at 10 years postvaccination. In subjects who received VAQTA® at 0 and 18 months, the GMT was 2501 mIU/mL (n=53) at 2.5 to 3.5 years, 1614 mIU/mL (n=56) at 5 to 6 years, and 1507 mIU/mL (n=41) at 10 years postvaccination. No data are currently available on the persistence of hepatitis A antibody when both doses are administered in children 12 through 23 months of age.

In studies of healthy adults who received two doses (~ 50 U) of VAQTA® at 0 and 6 months, the hepatitis A antibody response has been shown to persist at least 6 years. Detectable levels of anti-HAV antibodies (≥ 10 mIU/mL) were present in 100% (378/378) of subjects with a GMT of 1734 mIU/mL at 1 year, 99.2% (252/254) of subjects with a GMT of 687 mIU/mL at 2 to 3 years, 99.1% (219/221) of subjects with a GMT of 605 mIU/mL at 4 years, and 99.4% (170/171) of subjects with a GMT of 684 mIU/mL at 6 years postvaccination. After an initial decline over 2 years, the GMTs appeared to plateau during the 2 to 6 year period.

Data available from long term studies show persistence of antibodies up to 10 years in subjects who received 2 doses of VAQTA®. Although the total duration of the protective effect of VAQTA® in healthy, immunocompetent subjects is unknown, mathematical modelling using persistence data from subjects up to 41 years of age projects that at least 99% of subjects should remain seropositive (≥ 10 mIU anti-HAV/mL) for 25 years or possibly longer.

Interchangeability of the Booster Dose

A clinical study in 537 healthy adults, 18 to 83 years of age, evaluated the immune response to a booster dose of VAQTA® and Havrix* (hepatitis A vaccine, inactivated) given at 6 or 12 months following an initial dose of Havrix*. When VAQTA® was given as a booster dose following Havrix*, the vaccine produced an adequate immune response (see Table 7) and was generally well tolerated (see 4.2. Recommended Dose and Dosage Adjustment).

Table 7 - VAQTA® Versus Havrix* Seropositivity Rate, Booster Response Rate† and Geometric Mean Titer at 4 Weeks Postbooster

First Dose	Booster Dose	Seropositivity Rate	Booster Response Rate†	Geometric Mean Titer
Havrix* 1440 EL.U.	VAQTA® 50 U	99.7% (n=313)	86.1% (n=310)	3272 (n=313)
Havrix* 1440 EL.U.	Havrix* 1440 EL.U.	99.3% (n=151)	80.1% (n=151)	2423 (n=151)
† Booster Response Rate is defined as greater than or equal to a tenfold rise from prebooster to postbooster titer and postbooster titer ≥ 100 mIU/mL.				

Use With Other Vaccines

Protocol 057 – Clinical Study of VAQTA® with M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine, Live), VARIVAX® (Varicella Virus Vaccine Live), and Tripedia* (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)

A concomitant use study was conducted among 617 healthy children who were randomized to receive VAQTA® (~25 U) with or without M-M-R® II and VARIVAX® at ~12 months of age, and VAQTA® (~25 U) with or without DTaP vaccine (and an optional dose of polio vaccine) at ~18 months of age. In this study, the concomitant administration of VAQTA® with other vaccines at separate injection sites was generally well tolerated. The safety profile of VAQTA® administered alone at ~12 months and ~18 months of age was comparable to the safety profile of VAQTA® administered alone to children 2 to 16 years of age. The safety profile of the concomitant administration of VAQTA® with other vaccines at ~12 months and ~18 months of age was comparable to the safety profile of VAQTA® administered alone at ~12 months and ~18 months of age.

The hepatitis A response rates after each dose of VAQTA® when VAQTA® was given alone or concomitantly with M-M-R® II and VARIVAX® or DTaP and an optional dose of polio vaccine were similar. The hepatitis A response rates also were similar to predefined historical rates seen in 2- to 3-year-old children administered VAQTA® alone. When VAQTA® was administered concomitantly with M-M-R® II and VARIVAX®, the measles, mumps, and rubella response rates were similar to the historical rates for M-M-R® II. VAQTA® may be given concomitantly at separate injection sites with M-M-R® II. Data suggest that VAQTA® may be administered concomitantly with oral or inactivated polio vaccines. However, data from this study were insufficient to assess the immune response of DTaP when administered with VAQTA®. The immune responses to polio vaccine coadministered with VAQTA® are not available (see 4.4 Administration, Use With Other Vaccines).

Protocol 066 – Clinical Study of VAQTA® with ProQuad™ (Measles, Mumps, Rubella and Varicella [Oka/Merck] Virus Vaccine Live)

In a clinical trial involving 1800 healthy children 12 to 23 months of age, 1453 received two ~25U intramuscular doses of VAQTA®, and 347 were randomized to receive two ~25U intramuscular doses of VAQTA® concomitantly with 2 doses of ProQuad™ at least 6 months apart. Rates of solicited injection-site reactions (pain/tenderness, erythema, swelling) were higher than prior experience with VAQTA® in 12- to 23-month-old children. Rates of systemic adverse experiences and fever (≥38.9°C, Oral) were consistent with prior experience following 2 doses of VAQTA®.

Protocol 067 – Clinical Study of VAQTA® with ProQuad™ and Prevnar* (Pneumococcal 7-valent Conjugate Vaccine)

In a clinical trial involving 653 healthy children 12 to 15 months of age, 330 were randomized to receive VAQTA® (~ 25 U), ProQuad™, and Prevnar* concomitantly, and 323 were randomized to receive ProQuad™ and Prevnar* concomitantly followed by VAQTA® 6 weeks later. The seropositivity rate after 2 doses of VAQTA® given concomitantly with ProQuad™ and Prevnar* was 100% [95% CI: 98.0%, 100.0%] and for VAQTA® given without ProQuad™ and Prevnar* was 99.4% [95% CI: 96.5%, 100.0%]. Hepatitis A response was similar among the two groups who received VAQTA® with or without ProQuad™ and Prevnar*. Seroconversion rates and antibody titers for varicella and *S. pneumoniae* types 4, 6B, 9V, 14, 18C, 19F, and 23F were similar between the groups at 6 weeks post-vaccination. No clinically significant differences in adverse events were reported among treatment groups.

Protocol 068 – Clinical Study of VAQTA® with PedvaxHIB® (Haemophilus b conjugate vaccine (meningococcal protein conjugate), MSD Std.) and Infanrix* (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)

A concomitant use study was conducted among 617 healthy children who were randomized to receive VAQTA® (~25U) with or without PedvaxHIB® and Infanrix* at ~15 months of age. The observed hepatitis A seroresponse rate (percent with titer ≥ 10 mIU/mL) taken 4 weeks postdose 2 was 100% (n=208, 95% CI: 98.2%, 100.0%) in those who received VAQTA® concomitantly with PedvaxHIB® and Infanrix* or PedvaxHIB®. In those subjects who received VAQTA® alone, the observed hepatitis A seroresponse rate was 100% (n=183, 95% CI: 98.0%, 100.0%), regardless of baseline hepatitis A serostatus. The antibody response to hepatitis A was non-inferior when VAQTA® was administered concomitantly with either Infanrix* and PedvaxHIB® or PedvaxHIB® compared with when VAQTA® was administered alone. The antibody responses to Hib and pertussis PT, FHA, and pertactin were non-inferior when PedvaxHIB® or Infanrix* was administered concomitantly with VAQTA® compared with

nonconcomitant administration. The safety profile for VAQTA® was comparable when VAQTA® was given alone or concomitantly with Infanrix* and PedvaxHIB® or PedvaxHIB®.

Protocols 057, 067, and 068 – Integrated Summary of VAQTA® given with M-M-R® II, VARIVAX®, Tripedia*, ProQuad™, Prevnar*, PedvaxHIB® and Infanrix*

In three combined clinical studies (Protocols 057, 067, and 068), 1022 initially seronegative subjects received 2 doses of VAQTA® alone or concomitantly with other vaccines. Of the seronegative subjects, 99.9% achieved a titer ≥ 10 mIU/mL (95% CI: 99.5%, 100%). The antibody response to hepatitis A was non-inferior when VAQTA® was administered concomitantly with vaccines containing the following antigens: measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate, oral and inactivated polio, diphtheria toxoid, tetanus toxoid, acellular pertussis, and *Haemophilus influenzae b* vaccines.

Protocol 041 – Clinical Study of VAQTA® with Typhoid Vi Polysaccharide Vaccine and Yellow Fever Vaccine, Live Attenuated

A controlled clinical study was conducted with 240 healthy adults, 18 to 54 years of age, who were randomized to receive either VAQTA®, yellow fever and typhoid vaccines concomitantly at separate injection sites; yellow fever and typhoid vaccines concomitantly at separate injection sites; or VAQTA® alone. The seropositivity rate for hepatitis A when VAQTA®, yellow fever and typhoid vaccines were administered concomitantly was generally similar to when VAQTA® was given alone. The antibody response rates for yellow fever and typhoid were adequate when yellow fever and typhoid vaccines were administered concomitantly with and without VAQTA®. The concomitant administration of these three vaccines at separate injection sites was generally well tolerated (see 4.4 Administration, Use With Other Vaccines).

Subcutaneous Administration

In a clinical study with 114 healthy seronegative adults who received subcutaneous administration of VAQTA® (~50U), at 4 weeks following the first dose, the seropositivity rate (SPR) was 78%, and the GMT was 21 mIU/mL. At 24 weeks following the first dose and just prior to the second subcutaneous injection, the SPR was 95%, and the GMT was 153 mIU/mL. At 4 weeks following the second subcutaneous injection, the SPR was 100%, and the GMT was 1564 mIU/mL. The kinetics of seropositivity were slower for the first subcutaneous dose of VAQTA® compared with historical data for intramuscular administration. At 24 weeks following the first subcutaneous dose, the SPR was similar to the historical data at 4 weeks after the initial intramuscular dose. However, at 4 weeks following the second subcutaneous dose, the SPR was similar to the historical data 4 weeks after the second dose with intramuscular administration. Subcutaneous administration of VAQTA® was generally well tolerated.

Administration in HIV-Infected Adults

In a clinical study with 180 adults, 60 HIV-positive and 90 HIV-negative adults received VAQTA® (~50U) and 30 HIV-positive adults received placebo. At 4 weeks following the first dose of VAQTA®, the SPR was 61% for HIV-positive adults and 90% for HIV-negative adults. At 28 weeks following the first dose (4 weeks following the second dose) of VAQTA®, the SPRs were satisfactory for all groups: 94% (GMT of 1060 mIU/mL) in HIV-positive and 100% (GMT of 3602 mIU/mL) in HIV-negative adults. Furthermore, in the HIV-positive group receiving VAQTA®, the SPR was 100% (GMT of 1959 mIU/mL) in subjects with CD4 cell counts ≥300 cell/mm^3; however, the SPR was 87% (GMT of 517 mIU/mL) in subjects with CD4 cell counts <300 cell/mm^3. The kinetics of the immune response were slower in the HIV-positive group

compared with the HIV-negative group. In HIV-positive adults, administration of VAQTA® did not appear to adversely affect the CD4 cell counts and HIV RNA burden.

15. Microbiology

No microbiological information is required for this vaccine.

16. Non-Clinical Toxicology

Genotoxicity: VAQTA® has not been evaluated for its mutagenic potential.

Carcinogenicity: VAQTA® has not been evaluated for its carcinogenic potential.

Reproductive and developmental toxicology: VAQTA® has not been evaluated for its potential to impair fertility.

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.

This leaflet was prepared by Merck Canada Inc.

Date of Authorization: September 28, 2026

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