

## Name of Medicine

### VAQTA®

*Hepatitis A Vaccine, purified, inactivated*

Single dose 0.5 mL and 1.0 mL vials for intramuscular injection

## Presentation

A slightly opaque white sterile suspension after thorough agitation.

The vaccine is available in paediatric/adolescent 0.5 mL and adult 1.0 mL vials containing 25U and 50U of hepatitis A virus protein respectively.

Each 0.5 mL dose contains approximately 0.225 mg of aluminium provided as amorphous aluminium hydroxyphosphate sulfate and 35 mcg of sodium borate as a pH stabiliser, in 0.9% sodium chloride.

Each 1.0 mL dose contains approximately 0.45 mg of aluminium provided as amorphous aluminium hydroxyphosphate sulfate and 70 mcg of sodium borate as a pH stabiliser in 0.9% sodium chloride.

## Therapeutic Class

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

## Uses

### Actions

#### Hepatitis A Disease

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 faecal-oral route, with infection occurring within private households, daycare centres, 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 who is in the incubation phase of disease. 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 32,000 infections per year, of which 3,579 result in clinical hepatitis A disease, 549 hospitalisations, and 5 deaths due to fulminant hepatitis. Worldwide, it has been estimated that 1.4 million cases occur annually. The clinical manifestations of hepatitis A infection often pass unrecognised 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-coloured stools, abdominal pain, malaise, and fatigue.

### **Pharmacokinetics**

None

### **Indications**

VAQTA is indicated for active pre-exposure prophylaxis against disease caused by hepatitis A virus. Primary immunisation should be given at least 2 weeks prior to expected exposure to HAV.

Vaccination is recommended in children 12 months of age and older, adolescents, and adults who are at risk of contracting or spreading infection or who are at risk of life-threatening disease if infected, including but not limited to:

- travellers to endemic or outbreak areas
- frequently affected communities
  - members residing in any community with one or more recorded outbreaks within the last five years
- daycare
  - children and staff of daycare centres as well as their parents, siblings, and other contacts
- military personnel prior to departure for endemic or outbreak areas
- persons for whom hepatitis A is an occupational hazard
  - health-care workers
  - staff and residents of orphanages, chronic care hospitals and mental health care facilities
  - sewage workers
- haemophiliacs and other recipients of therapeutic blood products
- persons who test positive for hepatitis C virus and have diagnosed liver disease
- food handlers
- consumers of high-risk foods
  - e.g. raw shellfish
- persons at increased risk of the disease due to their sexual practices
  - homosexually-active males
  - persons who repeatedly contract sexually transmitted diseases
- human immunodeficiency virus (HIV)-infected adults
- users of illicit injectable drugs

VAQTA will not prevent hepatitis caused by infectious agents other than hepatitis A virus.

### **Revaccination**

See Dosage and Administration, *Booster Dose*.

### **Use With Other Vaccines**

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. Data on concomitant use with other vaccines are limited. (See Dosage and Administration, *Use with Other Vaccines*.)

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

The Advisory Committee on Immunization Practices, (ACIP advises the U.S. Public Health Service on vaccination policy), 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., travellers departing on short notice to endemic areas), VAQTA may be administered concomitantly with IG using separate sites and syringes (see Dosage and Administration).

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.

## **Dosage and Administration**

### **DO NOT INJECT INTRAVASCULARLY OR INTRADERMALLY**

VAQTA is for intramuscular injection. The deltoid muscle is the preferred site for intramuscular injection. While intramuscular injection results in the best immune response, VAQTA may be administered subcutaneously when clinically appropriate (See Warnings and Precautions).

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

### **Children/Adolescents**

Individuals 12 months through 17 years of age should receive a single 0.5 mL (~25U) dose of vaccine at elected date and a booster dose of 0.5 mL (~25U) 6 to 18 months later.

### **Adults**

Adults 18 years of age and older should receive a single 1.0 mL (~50U) dose of vaccine at elected date and a booster dose of 1.0 mL (~50U) 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.

### **Use with Other Vaccines**

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. Data on

concomitant use with other vaccines are limited (See Interactions, *Use with other vaccines*).

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

### **Known or Presumed Exposure to HAV/ Travel to Endemic Areas 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 manufacturer's product circular for the appropriate dosage for IG. A booster dose of VAQTA should be administered at the appropriate time as outlined above (see 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 medicine 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.

### **Contraindications**

Hypersensitivity to any component of the vaccine.

### **Warnings and Precautions**

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

Use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions.

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 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 unrecognised hepatitis A infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis A in such individuals.

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

VAQTA may be administered subcutaneously when clinically appropriate (e.g. people with bleeding disorders who are at risk of haemorrhage), 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.

### **Pregnancy**

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

### **Nursing Mothers**

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

### **Paediatric Use**

VAQTA has been shown to be generally well-tolerated and highly immunogenic in individuals 12 months through 17 years of age. See Dosage and Administration for the recommended dosage schedule.

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

### **Animal Toxicology**

Carcinogenesis, Mutagenesis, Reproduction

VAQTA has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

## **Adverse Effects**

### **Clinical Studies**

#### 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 >98.6oF 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.

The frequency classifications are as follows:  
Very Common ( $\geq 1/10$ ); Common ( $\geq 1/100$ ,  $< 1/10$ )

*Adverse Events in Children 12 Months Through 23 Months of Age Administered VAQTA Alone (At Both Doses):*

*Infections and infestations*

*Common:* Upper respiratory infection; otitis media; nasopharyngitis; rhinitis; viral infection; croup; gastroenteritis.

*Eye disorders*

*Common:* Conjunctivitis.

*Respiratory, thoracic and mediastinal disorders*

*Common:* Rhinorrhea; cough; nasal congestion.

*Gastrointestinal disorders*

*Common:* Diarrhea; vomiting; teething.

*Skin and subcutaneous tissue disorders*

*Common:* Dermatitis diaper; rash.

*General disorders and administration site conditions*

*Very Common:* Injection-site pain/tenderness/soreness; injection-site erythema; pyrexia (fever  $> 98.6^{\circ}\text{F}$  or feverish, Days 1-14); injection-site swelling; irritability.

*Common:* Fever  $> 102.2^{\circ}\text{F}$ , Oral (Days 1-5); injection-site bruising; injection-site hematoma.

*Adverse Events in Children 12 Months Through 23 Months of Age Administered VAQTA 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 (At Least One Dose):*

*Infections and infestations*

*Common:* Upper respiratory infection; otitis media; nasopharyngitis; viral infection; otitis; rhinitis; laryngotracheobronchitis.

*Metabolism and nutrition disorders*

*Common:* Decreased appetite.

*Nervous system disorders*

*Common:* Crying.

*Eye disorders*

*Common:* Conjunctivitis.

### *Respiratory, thoracic and mediastinal disorders*

*Common:* Rhinorrhea; cough; nasal congestion; respiratory congestion.

### *Gastrointestinal disorders*

*Common:* Diarrhea; vomiting.

### *Skin and subcutaneous tissue disorders*

*Common:* Rash; dermatitis diaper; measles-like/rubella-like rash.

### *General disorders and administration site conditions*

*Very Common:* Injection-site pain/tenderness/soreness; pyrexia (fever >98.6oF or feverish, Days 1-14); injection-site erythema; injection-site swelling; irritability.

*Common:* Fever ≥102.2oF, Oral (Days 1-5); injection-site bruising.

### Children/Adolescents - 2 through 17 Years of Age

In combined clinical trials involving 2595 healthy children (≥2 years of age) and adolescents (including the Monroe Efficacy Study, a placebo-controlled study of 1037 participants) who received one or more ~25U doses of hepatitis A vaccine, subjects were followed for fever and local complaints during a 5-day period post-vaccination and systemic complaints during a 14-day period post-vaccination. Injection-site complaints, generally mild and transient, were the most frequently reported complaints. Listed below are the complaints reported by ≥1% of subjects, without regard to causality, in decreasing order of frequency within each body system.

#### *Localised 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 (≥38.8°C (≥102°F), Oral (3.1%); abdominal pain (1.6%)

#### *Digestive System*

Diarrhoea (1.0%); vomiting (1.0%)

#### *Nervous System/Psychiatric*

Headache (2.3%)

#### *Respiratory System*

Pharyngitis (1.5%); upper respiratory infection (1.1%); cough (1.0%)

#### *Laboratory Findings*

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

### Adults - 18 Years of Age and Older

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

#### *Localised 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 ( $\geq 38.3^{\circ}\text{C}$  ( $\geq 101^{\circ}\text{F}$ ), Oral (2.6%); abdominal pain (1.3%)

#### *Digestive System*

Diarrhoea (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*

Pharyngitis (2.7%); upper respiratory infection (2.8%); 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.

### **Post-marketing Safety Study**

In a post-marketing safety study, a total of 42,110 individuals  $\geq 2$  years of age received 1 or 2 doses of VAQTA. There was no serious, vaccine-related, adverse event identified. There was no non-serious, vaccine-related, adverse event resulting in outpatient visits, with the exception of diarrhoea/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

#### *Haemic and Lymphatic System*

Very rarely; thrombocytopenia

## **Interactions**

### **Use with other Vaccines**

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. Data on concomitant use with other vaccines are limited (See Dosage and Administration, *Use with Other Vaccines*).

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

#### Protocol 057 - Clinical Study of VAQTA with M-M-R II, VARIVAX and Tripedia

A concomitant use study was conducted among 617 healthy children who were randomised to receive VAQTA (~25U) with or without M-M-R<sup>®</sup> II (Measles, Mumps, and Rubella Virus Vaccine Live) and VARIVAX<sup>®</sup> (Varicella Virus Vaccine Live [Oka/Merck]) at ~12 months of age, and VAQTA (~25U) with or without DTaP (Diphtheria, Tetanus, and acellular Pertussis) 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 vaccine. However, the data from this study were insufficient to assess the immune response of DTaP when administered with VAQTA. (See Dosage and Administration, *Use With Other Vaccines.*)

#### Protocol 066 – Clinical Study of VAQTA with ProQuad

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 ( $\geq 102.0^{\circ}\text{F}$  or  $38.9^{\circ}\text{C}$ , Oral) were consistent with prior experience following 2 doses of VAQTA.

#### Protocol 067 - Clinical Study of VAQTA with ProQuad and Prevenar

In a clinical trial involving 653 healthy children 12 to 15 months of age, 330 were randomised to receive VAQTA (~ 25U), ProQuad<sup>®</sup> (Measles, Mumps, Rubella and Varicella [Oka/Merck] Virus Vaccine Live, MSD), and Prevenar\* (Pneumococcal 7-valent Conjugate Vaccine) concomitantly, and 323 were randomised to receive ProQuad and Prevenar concomitantly followed by VAQTA 6 weeks later. The seropositivity rate after 2 doses of VAQTA given concomitantly with ProQuad and Prevenar was 100% (95% CI: 98.0%, 100.0%) and for VAQTA given without ProQuad and Prevenar 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 Prevenar. Seroconversion rates and antibody titres 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.

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\* Trademark of Wyeth Pharmaceuticals, Inc.

### Protocol 068 – Clinical Study of VAQTA with PedvaxHIB and INFANRIX

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  $\geq 10$  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, Prevenar, 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  $\geq 10$  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 randomised 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 Dosage and Administration, *Use With Other Vaccines*.)

The Advisory Committee on Immunisation Practices, (ACIP advises the U.S. Public Health Service on vaccination policy), 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., travellers departing on short notice to endemic areas), VAQTA may be administered concomitantly with IG using separate sites and syringes.

## Overdosage

There are no data with regard to overdose.

## Pharmaceutical Precautions

Store vaccine at 2-8°C (36-46°F).

DO NOT FREEZE since freezing destroys potency.

## Medicine Classification

Prescription Medicine

## Package Quantities

VAQTA adult is supplied as 1 mL single dose vials containing 50U hepatitis A virus protein.

VAQTA paediatric/adolescent is supplied as 0.5 mL single dose vials containing 25U hepatitis A virus protein.

## Further Information

### Chemistry

VAQTA (Hepatitis A Vaccine, Purified Inactivated) 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 developed at the Merck Research Laboratories, formalin inactivated, and then adsorbed onto amorphous aluminium hydroxyphosphate sulfate. One millilitre of the vaccine contains approximately 50 units (U) of hepatitis A antigen, which is highly purified and is formulated without a preservative. Within the limits of current assay variability, the 50U dose of VAQTA contains less than 0.1 mcg of non viral protein, less than  $4 \times 10^{-6}$  mcg of DNA, less than  $10^{-4}$  mcg of bovine albumin and less than 0.8 mcg of formaldehyde. Other process chemical residuals (including neomycin) are less than 10 parts per billion (ppb).

## Name and Address

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