

VAQTA Hepatitis A Vaccine, Inactivated

MIMS Abbreviated Prescribing Information

Hepatitis A vaccine

Merck Sharp & Dohme

Section: 10(a) Vaccines - Immunology

Use in pregnancy: B2

Permitted in sport

Use: Inactivated whole HAV vaccine. Active pre-exposure (greater than or equal to 2 wks) HAV prophylaxis in individuals greater than or equal to 12 mths, incl adults with HIV

Precautions: Immunosuppression; malignancy; latent HAV infection; acute, febrile illness; bleeding disorder (IM admin); SC admin (esp HIV); pregnancy, lactation, infants < 12 mths

Adverse Reactions: Inj site reaction; headache; GI upset; infants 12-23 mths: irritability, URTI, fever, otitis media; very rare: Guillain-Barre syndrome, encephalitis, thrombocytopenia; others, see full PI

VAQTA Paediatric/adolescent Formulation Injection Rx (S4) CMI

Inactivated whole HAV; Al hydroxide (adsorbant), borax (pH stabiliser), NaCl; sterile suspension; single dose prefilled syringe

Dose: Admin by IMI into deltoid (or SCI if appropriate): 1st dose at elected date, 2nd dose 6-18 mths later. Children, 12 mths-17 yrs: 0.5 mL/dose

Pack 25 U/0.5 mL [1] : \$45.10

VAQTA Adult Formulation Injection Rx (S4) CMI

Inactivated whole HAV; Al hydroxide (adsorbant), borax (pH stabiliser), NaCl; sterile suspension; single dose prefilled syringe

Dose: Admin by IMI into deltoid (or SCI if appropriate): 1st dose at elected date, 2nd dose 6-18 mths later. Adults greater than or equal to 18 yrs: 1.0 mL/dose; adults with HIV: 2nd dose at 6 mths. Use with other vaccines, Ig: see full PI

Pack 50 U/mL 1 mL [1] : \$69.92

MIMS Full Prescribing Information

MIMS revision date: 01 Sep 2008

Name of the medicine Inactivated hepatitis A vaccine.

Adult formulation. Active. Hepatitis A virus protein approximately 50 U/1 mL dose.

Inactive. Aluminium (as hydroxide) 0.45 mg/mL, borax 70 microgram/mL as a pH stabiliser; sodium chloride 0.9%.

Paediatric/adolescent formulation. Active. Hepatitis A virus protein approximately 25 U/0.5 mL dose.

Inactive. Aluminium (as hydroxide) 0.225 mg/0.5 mL, borax 35 microgram/0.5 mL as a pH stabiliser; sodium chloride 0.9%.

Description VAQTA is an inactivated whole virus vaccine derived from hepatitis A virus grown in cell culture in human MRC-5 diploid fibroblasts and has been shown to induce antibody to hepatitis A virus protein. 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, inactivated with formalin, and then adsorbed onto aluminium hydroxide. 1 mL 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 50 U dose of VAQTA contains less than 0.1 microgram of nonviral protein, less than 4×10^{-6} microgram of DNA, less than 10^{-4} microgram of bovine albumin and less than 0.8 microgram of formaldehyde. Other process chemical residuals are less than 10 parts per billion (ppb).

The manufacture of this product includes exposure to bovine related materials. No evidence exists that any case of variant Creutzfeldt-Jakob disease (vCJD) (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Clinical trials Clinical trials have been conducted worldwide with several formulations of the vaccine in 706 children 12 to 23 months of age and 8,361 healthy individuals ranging from 2 to 85 years of age.

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 IU/mL of hepatitis A antibody, measured by a modification of the HAVAB radioimmunoassay) and with an anamnestic antibody response following booster vaccination with VAQTA.

Immunogenicity. In a clinical study, 96% of 471 children ≈ 12 months of age seroconverted with a geometric mean titre of 48 mIU/mL within six weeks after the primary ≈ 25 U intramuscular dose of VAQTA. After each dose of VAQTA, the hepatitis A antibody titres 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 combined clinical studies, 97% of 1,214 children and adolescents 2 to 17 years of age seroconverted within four weeks after a single ≈ 25 U intramuscular dose of VAQTA. Similarly, 96% of 1,039 adults ≥ 18 years of age seroconverted within four 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 Persistence, below).

While a study evaluating VAQTA alone in a postexposure 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 1 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).

VAQTA**Table 1**

Seroconversion rates (%) after vaccination with VAQTA plus immune globulin (IG), Vaqta alone and IG alone

| Weeks after 1st dose | VAQTA plus IG | VAQTA | IG |
|----------------------|----------------|----------------|--------------|
| 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 was significantly higher than that in the vaccine plus IG group (p = 0.05)

** 4 weeks after 2nd dose given at 24 weeks

N/A Not applicable

Efficacy. The protective efficacy, immunogenicity and safety of VAQTA were evaluated in a randomised double blind placebo controlled study involving 1,037 susceptible healthy children and adolescents 2 to 16 years of age in a US community with recurrent outbreaks of hepatitis A (the Monroe efficacy study). Each child received a single intramuscular dose of VAQTA (approximately 25 U) or placebo. Among those individuals who were initially seronegative (by modified HAVAB), seroconversion was achieved in > 99% of vaccine recipients within four 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), the analysis of protective efficacy was based on cases of clinically confirmed hepatitis A occurring ≥ 50 days after vaccination in order to exclude any children incubating the infection before vaccination. The clinical case definition included all of the following occurring at the same time: one or more typical clinical signs or symptoms of hepatitis A (e.g. jaundice, malaise, fever $\geq 38.3^\circ\text{C}$); elevation of hepatitis A IgM antibody (HAVAB-M); elevation of alanine transferase (ALT) two or more times the upper limit of normal. In subjects who were initially seronegative, the protective efficacy of a single dose of VAQTA was observed to be 100% with 21 cases of clinically confirmed hepatitis A occurring in the placebo group and none in the vaccine group (p < 0.001). 28 cases of clinically confirmed hepatitis occurred in the placebo group while none occurred in the vaccine group ≥ 30 days after vaccination. In addition, it was observed in this trial that no cases of clinically confirmed hepatitis A occurred in the vaccine group after day 16. (One vaccinee did not meet the predefined criteria for clinically confirmed hepatitis A but did have positive hepatitis A IgM and borderline hepatic enzyme (ALT) elevations on days 34, 50 and 58 after vaccination with mild clinical symptoms observed on days 49 and 50.) 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.

No studies of the efficacy of VAQTA in children < 2 years of age were performed. Use in this group is supported by immunogenicity data alone. The presence of hepatitis A antibody has been used as a correlate of protection, and similarity of the immune response has been established between ≈ 12 month old children and 2 to 3 year old children.

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.

Follow-up surveillance in over 880 vaccine recipients for up to nine years after termination of the study showed that VAQTA continued to confer complete protection against clinical hepatitis A disease despite a small number of documented cases in the community among nonvaccinated individuals visiting or residing there. To date, no cases of hepatitis A disease ≥ 50 days after vaccination have occurred in those vaccinees from the Monroe efficacy study monitored for up to nine years.

In adults, seropositivity has been shown to persist up to 18 months after a single ≈ 50 U dose. Persistence of immunological memory was demonstrated with an anamnestic antibody response to a booster dose of ≈ 25 U given to children and adolescents 6 to 18 months after the primary dose, and to a booster dose of ≈ 50 U given to adults 6 to 18 months after the primary dose. 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, the hepatitis A antibody response to date has been shown to persist for up to six years (n = 274). The geometric mean titres (GMTs) tend to decline over time. There are no data on persistence of antibody in children who commenced vaccination at 12 to 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 to date has been shown to persist up to six years (n = 221). After an initial decline over two to three years, the GMTs appeared to plateau and were stable at the last assessment six years after the initial dosing.

Studies in healthy children, adolescents and adults to evaluate longer-term persistence and the need, if any, for additional booster doses are ongoing.

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; SmithKline Beecham Pharmaceuticals) given at six or twelve 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 2) and was generally well tolerated.

VAQTA**Table 2**

VAQTA versus Havrix seropositivity rate, booster response rate*, and geometric mean titre at four weeks post-booster

| First dose | Booster dose | Seropositivity rate | Booster response rate | Geometric mean titre |
|----------------------|----------------------|---------------------|-----------------------|----------------------|
| Havrix 1440 EL.U. | VAQTA 50 U | 99.7% (n = 313) | 86.1% (n = 310) | 3,272 (n = 313) |
| Havrix 1440 EL.U. | Havrix 1440 EL.U. | 99.3% (n = 151) | 80.1% (n = 151) | 2,423 (n = 151) |

* Booster dose response rate is defined as \geq tenfold rise from pre-booster to post-booster titre and a post-booster titre > 100 mIU/ml

Use with other vaccines. A concomitant use study was conducted among 617 healthy children who were randomised to receive VAQTA (≈ 25 U) with or without M-M-R II (measles, mumps and rubella virus vaccine live) and Varivax (Varicella virus vaccine live (Oka/Merck)) at ≈ 12 months of age, and VAQTA (≈ 25 U) 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 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 and ≈ 18 months of age was comparable to the safety profile of VAQTA administered alone at ≈ 12 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. Immunogenicity data are insufficient to support concomitant administration of VAQTA with Varivax or VAQTA with DTaP. The immune responses to polio vaccine coadministered with VAQTA are not available. (See Dosage and Administration, Use with other vaccines.)

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.

The immune response to polio vaccine, *Haemophilus influenzae* type b (HIB) conjugate vaccine, meningococcal polysaccharide vaccine and pneumococcal conjugate vaccine coadministered with VAQTA are not available (see Dosage and Administration, Use with other vaccines.)

Subcutaneous administration. In a clinical study with 114 healthy seronegative adults who received subcutaneous administration of VAQTA (≈ 50 U), at four 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 four weeks following the second subcutaneous injection, the SPR was 100%, and the GMT was 1,564 mIU/mL. The SPR and GMT measured four weeks after the first dose and the GMT after the second dose were lower than has historically been seen after intramuscular injection. At 24 weeks after the first dose, prior to the booster dose, the SPR was similar to that seen after intramuscular injection. Patients receiving VAQTA by subcutaneous injection should be advised that protection from infection is not reliably achieved until 24 weeks after the first dose. Subcutaneous injection was associated with a higher rate of local adverse events than intramuscular injection.

Administration in HIV infected adults. In a clinical study with 180 adults, 60 HIV positive and 90 HIV negative adults received VAQTA (≈ 50 U) and 30 HIV positive adults received placebo. At four 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 (four weeks following the second dose) of VAQTA, the SPRs were satisfactory for all groups: 94% (GMT of 1,060 mIU/mL) in HIV positive and 100% (GMT of 3,602 mIU/mL) in HIV negative adults. Furthermore, in the HIV positive group receiving VAQTA, the SPR was 100% (GMT of 1,959 mIU/mL) in subjects with CD4 cell counts ≥ 300 cells/mm³; however, the SPR was 87% (GMT of 517 mIU/mL) in subjects with CD4 cell counts < 300 cells/mm³. 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.

The immunogenicity of VAQTA after subcutaneous administration to HIV infected individuals has not been assessed.

Indications Active pre-exposure prophylaxis against disease caused by the hepatitis A virus in persons 12 months of age and older. Primary immunisation should be given at least two weeks prior to expected exposure to the hepatitis A virus. Individuals who are or will be at increased risk of infection include travellers to areas of intermediate or high endemicity for hepatitis A; persons for whom hepatitis A is an occupational hazard, i.e. employees of child day-care centres, certain institutional workers (e.g. caretakers for the intellectually disabled), healthcare workers and teachers in remote Aboriginal and Torres Strait Islander communities, nursing staff and other healthcare workers in contact with patients in paediatric wards and infectious disease wards; sewerage workers; recipients of blood products; individuals with chronic liver disease and those who have had a liver transplant; homosexually active males; human immunodeficiency virus (HIV) infected adults.

Contraindications Hypersensitivity to any component of the vaccine.

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

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 the hepatitis A virus. Because of the long incubation period (approximately 20 to 50 days) of 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 adrenaline, should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

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

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

VAQTA should be administered with caution to people with bleeding disorders who are at risk of haemorrhage following intramuscular injection.

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.

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

Use in pregnancy. (Category B2)

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.

Use in lactation. 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 breastfeeding.

Use in children. VAQTA has been shown to be generally well tolerated and highly immunogenic in individuals 12 months to 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.

Effect on ability to drive or operate machinery. There were no specific data. However, asthenia/ fatigue and headache have been reported following administration of VAQTA.

Interactions with other medicines Use with immune globulin. For subjects requiring postexposure prophylaxis or combined immediate and longer-term protection (e.g. travellers departing on short notice to endemic areas), VAQTA may be administered concomitantly with immune globulin using separate sites and syringes. Results from one clinical trial in adults support this regimen (see Actions, Pharmacology, Immunology).

Use with other vaccines. VAQTA may be given concomitantly with yellow fever, typhoid and M-M-R II vaccines. Immunogenicity data are insufficient to support concomitant administration of VAQTA with Varivax or VAQTA with DTaP. Data on concomitant use with other vaccines are limited (see Actions, Pharmacology, Use with other vaccines).

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

The Advisory Committee on Immunisation Practices (ACIP), which advises the US 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 simultaneously with hepatitis A vaccine without affecting either vaccine's or increasing the frequency of adverse events.

Adverse effects In combined clinical trials, VAQTA was administered to 706 children 12 to 23 months of age, and 8,361 healthy children, adolescents and adults and was generally well tolerated.

The Monroe efficacy study. In this study, 1,037 healthy children and adolescents 2 to 16 years of age received either a primary dose of \approx 25 U of hepatitis A vaccine and a booster 6, 12 or 18 months later, or placebo. Subjects were followed during a five 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 3 summarises the local and systemic complaints (\geq 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.

VAQTA

Table 3

Local and systemic complaints reported (\geq 1%) in healthy children and adolescents from the Monroe efficacy study

| Reaction | Treatment | | |
|----------------------------------|---------------|---------------|---------------|
| | Dose 1* | Booster | Placebo*# |
| 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 difference between the two groups

Second injection of placebo not administered because code for the trial was broken

Children 12 to 23 months of age. In combined clinical trials involving 706 healthy children 12 to 23 months of age who received one or more \approx 25 U doses of hepatitis A vaccine with or without other paediatric vaccines, subjects were followed for fever and local complaints during a five day period postvaccination and systemic complaints during a 14 day period postvaccination.

Irritability and upper respiratory infection were the most frequently reported complaints. Localised injection site complaints were generally mild and transient. The following list summarises the local and systemic complaints (\geq 1%) reported in these studies, without regard to causality, in decreasing order of frequency, within each body system.

Localised injection site reactions. Pain/ tenderness/ soreness 8.6%, erythema 5.9%, swelling 5.1%, warmth 3.2%, ecchymosis 1.0%.

Body as a whole. Fever (\geq 38.9°C, oral) 6.5%.

Digestive system. Diarrhoea 5.9%, vomiting 4.0%, anorexia 1.2%.

Nervous system/ psychiatric. Irritability 10.8%, crying 1.8%.

Respiratory system. Upper respiratory infection 10.1%, rhinorrhoea 5.7%, cough 5.1%, respiratory congestion 1.6%, nasal congestion 1.2%, laryngotracheobronchitis 1.2%.

Skin and skin appendages. Rash 4.5%, measles-like/ rubella-like rash 1.0%, viral exanthema 1.0%.

Special senses. Otitis media 7.6%, otitis 1.8%, conjunctivitis 1.3%.

Children and adolescents 2 to 17 years of age. In combined clinical trials (including Monroe efficacy study participants) involving 2,595 healthy children (\geq 2 years of age) and adolescents who received one or more \approx 25 U doses of hepatitis A vaccine, subjects were followed for fever and local complaints during a five 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. The following list summarises the local and systemic complaints (\geq 1%) reported in these studies, without regard to causality.

Local injection site reactions. Pain 18.5%, tenderness 16.7%, warmth 8.5%, erythema 7.4%, swelling 7.2%, ecchymosis 1.3%.

Body as a whole. Fever (oral temperature $\geq 38.9^{\circ}\text{C}$) 3.1%, abdominal pain 1.5%.

Gastrointestinal. Diarrhoea 1.0%, vomiting 1.0%.

Nervous system, psychiatric. Headache 2.3%.

Respiratory. Pharyngitis 1.5%, upper respiratory tract 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. In combined clinical trials involving 1,315 healthy adults who received one or more ≈ 50 U doses of hepatitis A vaccine, subjects were followed for fever and local complaints during a five 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. The following list summarises the local and systemic complaints ($\geq 1\%$) reported in these studies, without regard to causality.

Local injection site reactions. Tenderness 43.2%, pain 41.5%, warmth 11.1%, swelling 9.6%, erythema 9.4%, ecchymosis 1.3%, pain/ soreness 1.0%.

Body as a whole. Asthenia/ fatigue 3.0%, fever (oral temperature $\geq 38.3^{\circ}\text{C}$) 1.9%, abdominal pain 1.3%.

Gastrointestinal. Diarrhoea 2.0%, nausea 2.0%.

Musculoskeletal. Myalgia 1.7%.

Nervous system, psychiatric. Headache 11.6%.

Respiratory. Pharyngitis 2.6%, upper respiratory tract infection 2.4%.

Hypersensitivity reactions. 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 the use of VAQTA in very large populations might reveal adverse experiences not observed in clinical trials.

Postmarketing safety study. In a postmarketing safety study, a total of 42,110 individuals ≥ 2 years of age received one or two 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 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, encephalitis.

Haemic and lymphatic system. Very rarely, thrombocytopenia.

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 Precautions).

VAQTA does not contain a preservative. The vials and prefilled syringes are for use in a single patient only and any residual vaccine must be discarded.

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

Children, adolescents 12 months to 17 years of age. A single 0.5 mL (≈ 25 U) dose of vaccine at the elected date and a booster dose of 0.5 mL (≈ 25 U) 6 to 18 months later.

Adults ≥ 18 years of age. A single 1.0 mL (≈ 50 U) dose of vaccine at the 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 (≈ 50 U) dose of vaccine at elected date and a booster dose of 1.0 mL (≈ 50 U) six 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 and M-M-R II vaccines. Immunogenicity data are insufficient to support concomitant administration of VAQTA with Varivax or VAQTA with DTaP. 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 hepatitis A virus/ travel to endemic areas. Use with immune globulin. VAQTA may be administered concomitantly with immune globulin (IG) using separate sites and syringes. The vaccination regimen for VAQTA should be followed as stated above. Consult the manufacturer's product information for the appropriate dosage of IG. A booster dose of VAQTA should be administered at the appropriate time as outlined above (see also 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 discolouration 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.

Overdosage There are no data with regard to overdose.

Presentation Vaccine (sterile suspension), Adult (1.0 mL), Paediatric/ adolescent (0.5 mL): single dose vials and prefilled syringes.

Storage Store at 2 to 8°C . Storage above or below the recommended temperature may reduce potency. Do not freeze since freezing destroys potency.

Poison Schedule S4.

Source Reference Date of TGA approved information: 24/06/2008

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