VAQTA® Paediatric
(Hepatitis A Vaccine, inactivated, adsorbed)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Single dose prefilled syringe containing 0.5 ml of suspension. Each dose contains approximately 25 Units of hepatitis A virus antigen.

USES
For pre-exposure prophylaxis against disease caused by hepatitis A virus (HAV) in healthy individuals from 12 months to 17 years of age who are at risk of contracting or spreading infection or who are at risk of life-threatening disease if infected. Use in accordance with official recommendations.

DOSAGE AND ADMINISTRATION
Administer a single 0.5 mL (25U) dose of vaccine at an elected date and a booster dose of 0.5 mL (25U) 6 to 18 months after the first dose. Administer by intramuscular injection, preferably in the deltoid muscle. The anterolateral thigh region may be used in infants if the deltoid muscle is not sufficiently developed. Do not administer intradermally or intravenously. Administer subcutaneously when clinically appropriate e.g. for individuals with bleeding disorders who are at risk of haemorrhage. Primary immunisation should be given at least 2, preferably 4, weeks prior to expected exposure to HAV. It is predicted that hepatitis A antibodies will remain at least 25 years after vaccination. Interchangeability of booster dose: a booster dose may be given 6 to 12 months following the initial dose of another inactivated HAV vaccine, as shown by data for adults. Immunoglobulin may be given at the same time but using separate sites and syringes. Use with other vaccines: similar Hepatitis A response shown when given alone or concomitantly with measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate, inactivated polio, diphtheria toxoid, tetanus toxoid, acellular pertussis, or Haemophilus influenzae b vaccine. VAQTA Paediatric must not be mixed with other vaccines in the same syringe. When concurrent administration is necessary, use different injection sites and separate syringes.

CONTRA-INDICATIONS
Hypersensitivity to any component of the vaccine. Delay vaccination in the presence of severe febrile infections.

PRECAUTIONS
Prophylactic use only. Individuals who develop symptoms suggestive of hypersensitivity after an injection of VAQTA Paediatric should not receive further injections. Ensure adequate treatment, including epinephrine, is available for immediate use in case of anaphylaxis. The vaccine does not give immediate protection and if hepatitis A infection is present at the time of vaccination, the vaccine may be ineffective. If used in individuals with malignancies or those receiving immunosuppressive therapy or who are otherwise immunocompromised, the expected immune response may not be obtained. Do not mix with other vaccines, immunoglobulin, or other medicinal products in the same syringe. Other vaccines given at the same time should be administered at different sites. It may be given concomitantly with yellow fever, polysaccharide typhoid, measles, mumps, rubella, varicella, pneumococcal 7-valent conjugate, inactivated polio, diphtheria toxoid, tetanus toxoid, acellular pertussis, or Haemophilus influenzae b vaccines. Use with caution in latex-sensitive individuals: syringe plunger stopper and tip cap contain dry natural latex rubber. This vaccine may contain traces of neomycin and formaldehyde which are used during the manufacturing process. Vaccination not result in a protective response in all susceptible vaccinees. *Pregnancy and lactation*: Not recommended during pregnancy unless benefits outweigh risks. Exercise caution in breastfeeding women.

SIDE EFFECTS

Refer to Summary of Product Characteristics for complete information on side-effects.

-12 months through 23 months of age: *very common*: injection site pain/tenderness, erythema; common: fever, irritability, diarrhoea and swelling, warmth, bruising at injection site. - **2 years through 17 years of age**: *very common*: injection site pain, tenderness. *Common:* injection site reactions (warmth, erythema, swelling and ecchymosis), fever and headache. In post-marketing experience, cases of Guillain-Barré syndrome and haematologic autoimmune diseases like thrombocytopenia have been reported. As with all vaccines, allergic reactions, in rare cases leading to shock, may occur.

PACKAGE QUANTITIES AND BASIC NHS COST

1 one single dose prefilled syringe; basic NHS cost £14.74.

Marketing Authorisation number:

PL 53095/0008

Marketing Authorisation Holder:

Merck Sharp & Dohme (UK) Limited
120 Moorgate
London EC2M 6UR
United Kingdom

Legal category: POM

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