VAQTA® Adult
(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 or suspension for injection in a vial containing 1.0 ml of suspension. Each dose contains approximately 50 Units of hepatitis A virus antigen.

USES
For pre-exposure prophylaxis against disease caused by hepatitis A virus (HAV) in adults (18 years of age and older) 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 1.0 mL (50U) dose of vaccine at an elected date and a booster dose of 1.0 mL (50U) 6 to 18 months after the first dose. Administer by intramuscular injection in the deltoid region. 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. HIV-infected adults should receive a single dose of 1.0mL (50U) of VAQTA Adult at an elected date followed by a booster dose of 1.0mL (50U) 6 months later. It is predicted that hepatitis A antibodies will remain at least 25 years after vaccination. Interchangeability of booster dose: a booster dose may also be given 6 to 12 months following the initial dose of another inactivated HAV vaccine. Immunoglobulin may be administered at the same time but using separate sites and 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 Adult 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 against hepatitis A and there may be a period of 2 to 4 weeks before antibody becomes detectable. 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 and inactivated polio vaccines. Use with caution in latex-sensitive individuals: syringe plunger stopper and tip cap, and vial rubber stopper contain dry natural latex rubber. This vaccine may contain traces of neomycin and formaldehyde which are used during the manufacturing process. Vaccination may 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.
Very common: tenderness, pain, warmth, swelling and erythema at injection site. *Common:* headache, arm pain (in the injected arm), asthenia/fatigue, fever (≥38.3ºC oral), injection-site ecchymosis, and pain/soreness. In post-marketing experience, cases of Guillain-Barré syndrome and haematologic autoimmune diseases like thrombocytopaenia have been reported. As with all vaccines, allergic

reactions, in rare cases leading to shock, may occur.

PACKAGE QUANTITIES AND BASIC NHS COST
Pack containing one single dose prefilled syringe or one suspension for injection in a vial: basic NHS cost £18.10.

Marketing Authorisation number:
PL 53095/0007

Marketing Authorisation Holder:
Merck Sharp & Dohme (UK) Limited,
120 Moorgate, London EC2M 6UR,
United Kingdom

Legal category: POM

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