

Prescribing Information - Refer to SPC before prescribing.

Havrix Monodose and Havrix Junior Monodose Hepatitis A (inactivated) vaccine (adsorbed). **Uses:** immunisation against hepatitis A. **Dosage and administration:** i.m. use in the deltoid region or anterolateral thigh in young children. *Adults (16 years and over):* 1.0 ml Havrix Monodose (1440 ELISA units/ml). *Children/adolescents (1-15 years):* 0.5 ml Havrix Junior Monodose (720 ELISA units) 2-4 weeks before risk of exposure. A booster dose is recommended 6-12 months after first dose for more persistent immunity. Booster dose can be given up to 36 months from primary schedule. For adults, it is unnecessary to restart the primary vaccination schedule if the booster is administered within 5 years of the primary vaccination. **Contra-indications:** Hypersensitivity to any component or neomycin. **Precautions:** Immunisation should be postponed in subjects suffering from acute severe febrile illness. Have adrenaline available for immediate use in case of anaphylaxis. May not prevent hepatitis A if immunisation occurs during incubation period of hepatitis A infection. Haemodialysis and immunocompromised patients may need additional doses. **Interactions:** For information on the concomitant use with other vaccines please refer to the SPC. Simultaneous administration with normal immunoglobulin may result in a lower antibody

titre. Give concomitant vaccines by separate injections into different body sites. **Pregnancy and lactation:** Use only when clearly needed. Caution in breastfeeding. **Adverse reactions:** See SPC for full details. *Common:* headache, injection site reactions, fatigue, loss of appetite, GI symptoms, fever, malaise, irritability. *Serious:* anaphylaxis, convulsions, neurological disorders such as Guillain Barre Syndrome, neuralgic amyotrophy, vasculitis, angioneurotic oedema. **Legal category:** POM. **Presentation and basic NHS cost:** Havrix Monodose 1ml pre-filled syringe. 1, £22.14; 10, £221.43. 1ml vial. 1, £22.14; 10, £221.43. Havrix Junior Monodose 0.5ml pre-filled syringe. 1, £16.77; 10, £167.68. 1ml vial. 1, £16.77; 10, £167.68. **MA number:** PL 10592/0037, PL 10592/0080. **MA holder:** SmithKline Beecham Ltd. Trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, UB11 1BT. **Further information is available from:** Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. Havrix Monodose and Havrix Junior Monodose are registered trademarks of the GlaxoSmithKline group of companies. **Date of preparation:** July 2015 UK/VAC/0088/15

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.