Prescribing Information

Please consult the Summary of Product Characteristics (SPC) before prescribing.

Havrix Monodose and Havrix Junior Monodose Hepatitis A (inactivated) vaccine (adsorbed). Suspension for injection in a pre-filled syringe.

Composition: 1.0 ml Havrix Monodose contains 1440 ELISA units of hepatitis A virus (inactivated); 0.5 ml Havrix Junior Monodose contains 720 ELISA units; both compositions adsorbed on aluminium hydroxide, hydrated. May contain traces of neomycin B sulfate. Contains phenylalanine: 83 µg (Junior Monodose) / 166 µg (Havrix Monodose) in each dose. **Uses:** Active immunisation against infection caused by hepatitis A virus. The vaccine is particularly indicated for those at increased risk of infection or transmission.

Dosage and administration: *Adults (16 years and over):* 1.0 ml Havrix Monodose. *Children/adolescents (1-15 years):* 0.5 ml Havrix Junior Monodose 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. Inject intramuscularly in the deltoid region or anterolateral thigh in young children, not to be administered in the gluteal region. Havrix should never be administered intravascularly. Havrix should not be administered subcutaneously/intradermally since administration by these routes may result in a less than optimal anti-HAV antibody response. In subjects with a bleeding disorder who are at risk of hemorrhage following intramuscular injection, this vaccine may be administered by deep subcutaneous injection as per local guidance. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes.

Contraindications: Hypersensitivity to the active substance, to any of the excipients, or to neomycin.

Precautions: Immunisation should be postponed in subjects suffering from acute severe febrile illness. Have adrenaline available for immediate use in case of anaphylaxis. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. May not prevent hepatitis A if immunisation occurs during incubation period of hepatitis A infection. Haemodialysis and immunocompromised patients may need additional doses. Havrix vaccines contain phenylalanine which may be harmful to patients that have phenylketonuria (PKU).

Interactions: For information on the concomitant use with other vaccines please refer to the SPC. Give concomitant vaccines by separate injections into different body sites. Simultaneous administration with normal immunoglobulin may result in a lower antibody titre. **Pregnancy and lactation:** There are limited amount of data from the use of this vaccine in pregnant women. Use only when clearly needed. Caution in breastfeeding.

Adverse reactions: See SPC for full details.

Havrix Monodose: *Very common: headache*, pain and redness at the injection site, fatigue. *Common:* loss of appetite, gastrointestinal symptoms, nausea, diarrhoea, fever, malaise, injection site reaction, such as swelling or induration. *Serious:* anaphylaxis, convulsions, Guillain Barre Syndrome, neuralgic amyotrophy, transverse myelitis, vasculitis, angioneurotic oedema.

Havrix Junior Monodose: *Very common:* irritability, pain and redness at the injection site. *Common:* headache, loss of appetite, nausea, fever, drowsiness, malaise. *Serious:* anaphylaxis, convulsions, Guillain Barre Syndrome, neuralgic amyotrophy, transverse myelitis, vasculitis, angioneurotic oedema.

Legal category: POM. **Presentation and basic NHS cost:** Havrix Monodose 1ml pre-filled syringe. 1, £22.14; 10, £221.43. Havrix Junior Monodose 0.5ml pre-filled syringe. 1, £16.77; 10, £167.68. **MA numbers:** PL 10592/0037, PL 10592/0080. **MA holder:** SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex TW8 9GS. Trading as GlaxoSmithKline UK. **Further information is available from:** GlaxoSmithKline Customer Contact Centre; customercontactuk@gsk.com; Freephone 0800 221 441. Havrix Monodose and Havrix Junior Monodose are registered trademarks of the GlaxoSmithKline group of companies.

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline 0800 221 441.