

Prescribing Information – Refer to SPC before prescribing.

Ambirix (Hepatitis A (inactivated) and Hepatitis B (rDNA) (HAB) vaccine (adsorbed)) **Indication:** Immunisation against hepatitis A and hepatitis B infection from 1 year up to and including 15 years of age. **Dosage and administration:** 1ml (720 ELISA HA/20 µg HBsAg) by i.m. injection usually into the deltoid muscle at the elected date and a second dose 6 to 12 months after the first dose. **Contraindications:** Hypersensitivity to any component or neomycin or hypersensitivity after previous administration of hepatitis A and/or hepatitis B vaccines. Acute severe febrile illness. **Precautions:** Protection may not occur until after second dose. Avoid gluteal or intradermal injection. Adequate response may not be achieved in immunocompromised patients. If rapid protection against hepatitis B is required, use three-dose regimen of combined (360 ELISA units HA/10µg HBsAg). **Interactions:** Satisfactory antibodies titres seen when administered concomitantly with DTPa-IPV+Hib or MMR vaccines in second year of life. Concomitant administration with other vaccines not recommended unless absolutely necessary. Use different injection sites, preferably different limbs, if

administering Ambirix with other vaccines. **Pregnancy and lactation:** Ambirix should only be used when the possible advantages outweigh the potential risks. **Adverse reactions:** See SPC for full details. *Common:* headache, appetite loss, injection site reactions, fatigue and irritability, drowsiness, GI symptoms, fever. *Serious:* anaphylaxis, meningitis, thrombocytopenia, angioneurotic oedema, multiple sclerosis, neurological disorders such as Guillain-Barré syndrome, encephalitis, encephalopathy, convulsions, paralysis, vasculitis. **Legal category:** POM. **Presentation and basic NHS cost:** Ambirix pre-filled 1.0ml syringe. 1 unit, £31.18. **Marketing Authorisation number:** EU/1/02/224/001-5. **MA holder:** GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, B-1330 Rixensart, Belgium. Further information available from: Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. **Date of preparation:** July 2015 UK/VAC/0070/15. Ambirix is a registered trademark of the GlaxoSmithKline group of companies.

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