Prescribing Information (United Kingdom)
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. Hepatitis B protection may not occur until after second dose. Use only when relatively low risk of hepatitis B infection during course. Should be administered in a setting where completion of course can be assured.

Dosage and administration: 1ml (720 ELISA HA/20 µg HBsAg) by intramuscular injection at the elected date and a second dose six to 12 months after the first dose. Recommendations for boosting Ambirix: same as for monovalent hepatitis A or B vaccines.

Contraindications: Hypersensitivity to any component or neomycin or hypersensitivity after previous administration of hepatitis A and/or hepatitis B vaccines. Acute severe febrile illness.

Special Warnings and Precautions: Not recommended for postexposure prophylaxis. Rare anaphylactic reactions. Two-dose course should be completed prior to start of sexual activity. Do not administer intravascularly. 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). Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic clonic movements during recovery. It is important that procedures are in place to avoid injury from faints.

Interactions: No data on concomitant administration with specific hepatitis A or hepatitis B immunoglobulin. 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.

Fertility, pregnancy and lactation: No fertility data are available. Ambirix can be used during pregnancy only when clearly needed, and the possible advantages outweigh the potential risks for the foetus. Ambirix should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Side Effects: *Very common (≥1/10):* headache, appetite loss, pain/redness at injection site, fatigue and irritability. *Common (≥1/100 to <1/10):* drowsiness, gastrointestinal symptoms, swelling at injection site, fever. *Post-marketing reactions reported following vaccination with Ambirix are:* allergic reactions including anaphylaxis and anaphylactoid reactions, syncope or vasovagal responses to injection, localised hypoaesthesia. The following adverse reactions were reported during clinical trials with GlaxoSmithKline's other combined hepatitis A and hepatitis B vaccines (given as a 3 or 4 dose schedule): *Common (≥1/100 to <1/10)*: diarrhoea, nausea, malaise, injection site reaction. *Uncommon (≥1/1,000 to <1/100)*: upper respiratory tract infection, dizziness, vomiting, abdominal pain, myalgia. *Rare(≥1/10,000 to <1/1000):* lymphadenopathy, paraesthesia, hypotension, pruritus, rash, arthralgia, chills, influenza like illness. *Very rare (< 1/10,000):* urticaria. Following widespread use of GlaxoSmithKline's combined hepatitis A and hepatitis B vaccines or the monovalent hepatitis A and/or hepatitis B vaccines, the following adverse reactions have additionally been reported: meningitis, thrombocytopenia, thrombocytopenic purpura, allergic reactions including mimicking serum sickness, angioneurotic oedema, multiple sclerosis, myelitis, facial palsy, polyneuritis such as Guillain-Barré syndrome (with ascending paralysis), encephalitis, encephalopathy, neuritis, optic neuritis, neuropathy, convulsions, paralysis, vasculitis, abnormal liver function tests, erythema multiforme, lichen planus, arthritis, muscular weakness, immediate injection site pain, stinging and burning sensation.

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.

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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

Please refer to the full Summary Product Characteristics before prescribing