Ambirix (Hepatitis A (inactivated) and Hepatitis B (rDNA) (HAB) vaccine (adsorbed)) PRESCRIBING INFORMATION

Please find below:

1. **PRESCRIBING INFORMATION for Great Britain (GB)**
2. **PRESCRIBING INFORMATION for Northern Ireland (*which is located below the GB Prescribing Information*)**

PRESCRIBING INFORMATION - Great Britain

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

Ambirix (Hepatitis A (inactivated) and Hepatitis B (rDNA) (HAB) vaccine (adsorbed)).

Composition: 1 dose (1 ml) contains 720 ELISA Units of Hepatitis A virus (inactivated) adsorbed on aluminium hydroxide and 20µg of HBsAg adsorbed on aluminium phosphate.

Indication: Immunisation against hepatitis A and hepatitis B infection in non-immune children and adolescents from 1 year up to and including 15 years of age. Protection against hepatitis B infections may not be obtained until after the second dose. Ambirix should be used only when there is a relatively low risk of hepatitis B infection during the vaccination course and should be administered in settings where completion of the two-dose vaccination course can be assured.

Dosage and administration: 1ml by intramuscular injection usually into the deltoid muscle. The primary course of vaccination consists of 2 doses, the first at the elected date and a second dose 6 to 12 months after the first dose. Exceptionally, the vaccine may be administered subcutaneously in patients with thrombocytopenia or bleeding disorders, but this may result in suboptimal immune response to the vaccine. **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: Appropriate medical treatment should be available in case of rare anaphylactic reaction after vaccination. Syncope (fainting) can occur following, or even before, any vaccination. Avoid gluteal or intradermal injection due to suboptimal response and in no circumstances administer intravascularly. Protection may not occur until after second dose. Adequate response may not be achieved in immunocompromised patients. Ambirix is not recommended for postexposure prophylaxis. If rapid protection against hepatitis B is required, use three-dose regimen of combined vaccine (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. *Very common and common*: headache, swelling at the injection site, pain and redness at the injection site, appetite loss, injection site reactions, malaise, fatigue and irritability, drowsiness, GI symptoms, diarrhoea, nausea, fever. *Serious*: anaphylaxis, meningitis, thrombocytopenia, angioneurotic oedema, vasculitis, neurological disorders such as multiple sclerosis, Guillain-Barré syndrome, encephalitis, encephalopathy, convulsions, paralysis.

Legal category: POM. **Presentation and basic NHS cost:** Ambirix pre-filled 1.0ml syringe. 1 unit, £31.18.

Marketing Authorisation number: PLGB 19494/0259. **MA holder:** GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom. **Further information** is available from GSK Customer Contact Centre: customercontactuk@gsk.com; Freephone 0800 221 441. Ambirix is a registered trademark of the GlaxoSmithKline group of companies.

Date of preparation: November 2023.

Ref: PI-0500 (V5.0).

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.

PRESCRIBING INFORMATION – Northern Ireland

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

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Composition: 1 dose (1 ml) contains 720 ELISA Units of Hepatitis A virus (inactivated) adsorbed on aluminium hydroxide and 20µg of HBsAg adsorbed on aluminium phosphate.

Indication: Immunisation against hepatitis A and hepatitis B infection in non-immune children and adolescents from 1 year up to and including 15 years of age. Protection against hepatitis B infections may not be obtained until after the second dose. Ambirix should be used only when there is a relatively low risk of hepatitis B infection during the vaccination course. Ambirix should be administered in settings where completion of the two-dose vaccination course can be assured.

Dosage and administration: 1ml by i.m. injection usually into the deltoid muscle. The primary course of vaccination consists of 2 doses, the first at the elected date and a second dose 6 to 12 months after the first dose. Exceptionally, the vaccine may be administered subcutaneously in patients with thrombocytopenia or bleeding disorders, but this may result in suboptimal immune response to the vaccine.

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: Appropriate medical treatment should be available in case of rare anaphylactic reaction after vaccination. Syncope (fainting) can occur following, or even before, any vaccination. Avoid gluteal or intradermal injection due to suboptimal response and in no circumstances administer intravascularly. Protection may not occur until after second dose. Adequate response may not be achieved in immunocompromised patients. Ambirix is not recommended for postexposure prophylaxis. If rapid protection against hepatitis B is required, use three-dose regimen of combined vaccine (360 ELISA units HA/10µg HBsAg).

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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** is available from GSK Customer Contact Centre: customercontactuk@gsk.com; Freephone 0800 221 441. Ambirix is a registered trademark of the GlaxoSmithKline group of companies.

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