***Twinrix* Adult and *Twinrix* Paediatric (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.

***Twinrix* Adult and *Twinrix* Paediatric** (Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)). **Composition:** Twinrix Adult: 1 dose (1ml) contains 720 ELISA units Hepatitis A virus inactivated /20 µg HBsAg adsorbed on aluminium hydroxide and phosphate respectively. Twinrix Paediatric: 1 dose (0.5ml) contains 360 ELISA units hepatitis A virus (inactivated)/10 µg HBsAg adsorbed on aluminium hydroxide and phosphate respectively.

Uses: Active immunisation against hepatitis A and B virus infection for those at risk of both hepatitis A and hepatitis B infection. Twinrix Adult: for use in adults and adolescents 16 years of age and above. Twinrix Paediatric: for use in infants, children and adolescents from 1 year up to and including 15 years.

Dosage and administration: Three doses (at 0, 1 and 6 months). When necessary due to timing of travel, for more rapid protection in adults (18 years and above): use 0, 7 and 21 days and a fourth dose is recommended at 12 months. *Adults and adolescents 16 years and abo*ve: 1 ml i.m. (deltoid); *Children 1 - 15 years*: 0.5 ml i.m (deltoid, or anterolateral thigh in infants). **Contra-indications:** Hypersensitivity to any active substances or excipients, neomycin or previous hepatitis A or B vaccines. Acute severe febrile illness.

Precautions: Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event. Syncope (fainting) can occur following, or even before, any vaccination. Not recommended for post-exposure prophylaxis. In haemodialysis patients and persons with an impaired immune system, anticipated immune response may not be achieved after the primary immunisation course and may therefore require additional doses of vaccine. In these patients, an adequate response may not be achieved. Consider serological testing of subjects at risk of not achieving seroprotection following a complete course of *Twinrix* Adult. Avoid intradermal injection or intramuscular administration into gluteal muscle due to suboptimal response. Do not administer intravascularly under any circumstances. Subcutaneous administration may be considered for those with bleeding disorders, but it may result in suboptimal immune response.

Interactions: For information on the concomitant use of *Twinrix* Paediatric/Adult with other vaccines please refer to the SPC.

Pregnancy: Vaccination should be delayed until after delivery unless there is an urgent need to protect mother against hepatitis B infection.

Lactation: It is unknown whether Twinrix is excreted in human breast milk. Caution in breast-feeding.

Adverse reactions: See SPC for full details. *Very common and common*: loss of appetite, headache, pain and redness at the injection site, swelling at injection site, injection site reactions, fatigue, drowsiness, irritability, GI symptoms, diarrhoea, nausea, malaise, fever. *Serious*: anaphylaxis, thrombocytopenia, angioneurotic oedema, meningitis, vasculitis, abnormal liver function tests, neurological disorders such as Guillain-Barré syndrome, encephalitis, encephalopathy, convulsions, paralysis, multiple sclerosis, optic neuritis. **Legal category:** POM. **Presentation and basic NHS cost:** *Twinrix* Adult pre-filled 1.0ml syringe. 1, £33.31; 10, £333.13. *Twinrix* Paediatric pre-filled 0.5ml syringe. 1, £20.79. **MA number**: Twinrix Adult: PLGB 19494/0265; Twinrix Paediatric: PLGB 19494/0266. **MA holder:** GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom. For the UK, further information is available from the GSK Customer Contact Centre: customercontactuk@gsk.com; Freephone: 0800 221 441. *Twinrix* is a registered trademark 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 on 0800 221 441

PRESCRIBING INFORMATION - Northern Ireland

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