Prescribing Information

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

INFANRIX-IPV+Hib – Diphtheria, tetanus, pertussis (acellular component), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed). **Composition**: A 0.5ml dose of vaccine contains suspension of diphtheria toxoid ≥ 30 IU, tetanus toxoid ≥ 40IU, *Bordetella pertussis* antigens adsorbed on aluminium hydroxide (pertussis toxoid 25µg, filamentous haemagglutinin 25µg and pertactin 8µg), poliovirus (inactivated, type 1 Mahoney strain, type 2 MEF-1 strain and type 3 Saukett strain, 40, 8 and 32 D-antigen units respectively) and, provided as powder for suspension, *H. influenzae* type b polysaccharide 10µg conjugated to tetanus toxoid (approx 25µg). Excipients: para-aminobenzoic acid <0.07 nanograms, phenylalanine 0.036 micrograms, <1mmol sodium and <1mmol potassium per dose.

Uses: Active immunisation of children from 2 months of age, against diphtheria, tetanus, pertussis, poliomyelitis and *H. influenzae* type b.

Dosage and administration: Requires reconstitution, refer to SPC for instructions. Use immediately after reconstitution. Primary vaccination: 2 or 3 doses in accordance with official recommendations. Administer first dose from age of 2 months, with subsequent doses separated by a minimum interval of 4 weeks. For deep intramuscular injection into anterolateral aspect of thigh. Use alternate limbs for each subsequent dose. Booster vaccination: After 2 primary doses, to be given at least 6 months after last priming dose. After 3 primary doses, a booster dose of Hib conjugate vaccine (monovalent or combined) must be administered. Booster vaccinations should be given in accordance with official recommendations. Use with caution in patients with bleeding disorders. Do not administer intravascularly.

Contraindications: See SmPC for details. Hypersensitivity after previous administration with diphtheria, tetanus, pertussis, polio or Hib vaccines. Hypersensitivity to neomycin, formaldehyde, polymyxin or any component of the vaccine. Encephalopathy of unknown aetiology within 7 days of previous vaccination against pertussis. Postpone in children with acute severe febrile illness.

Special warnings and precautions: See SmPC for full list. Appropriate medical treatment and supervision should be available in case of anaphylactic reaction following administration of the vaccine. Safety and efficacy of Infanrix-IPV+Hib have not been established in children over 3 years. Exercise caution if previous DTP vaccination was followed by fever (≥40°C), hypotonic, or hyporesponsive state or persistent crying within 48 hours, or convulsions within 3 days. Consider risk-benefit in children with severe neurological disorder. Immune response may be compromised in immunosuppressed patients. Respiratory monitoring may be required in very premature infants. Syncope can occur following or before needle injection, procedures should be in place to avoid injury from faints. Para-aminobenzoic acid may cause allergic reactions. Phenylalanine may be harmful in phenylketonuria. Record name and batch number.

Interactions: Administer at different injection sites if given with other vaccinations.

Adverse Reactions: See SmPC for full details. Very common: Loss of appetite, abnormal crying, irritability, restlessness, somnolence, fever ≥38°C, injection site reactions such as pain and redness, local swelling at injection site (≤50mm). Common: diarrhoea, vomiting, injection site reactions including induration, local swelling (>50mm). Post marketing surveillance – frequency unknown: allergic reactions including anaphylactic and anaphylactoid reactions, hypotonic-hyporesponsive state, convulsions, apnoea, angioneurotic oedema, swelling of entire injected limb, injection site vesicles. **Legal Category:** POM. **MA number:** PL 10592/0216. **Presentation and Basic NHS cost:** 0.5 ml of suspension for injection in a pre-filled syringe (pack of 1): £27.86. **MA Holder:** SmithKline Beecham Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS. Trading as GlaxoSmithKline UK. **Further information** is available from the GSK Customer Contact Centre: customercontactuk@gsk.com, Freephone 0800 221 441. Infanrix-IPV+HIB is a registered trademark of the GlaxoSmithKline group of companies.

Date of preparation: June 2022. **Ref:** PI-0509 (V4).

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