Prescribing Information

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

MENITORIX *Haemophilus* type b (Hib) and Meningococcal group C (MenC) conjugate vaccine. **Composition:** Each 0.5ml dose contains 5µg Hib polysaccharide (polyribosylribitol phosphate) and 5µg Neisseria meningitidis group C (strain C11) polysaccharide conjugated to 12.5µg and 5µg tetanus toxoid as a carrier protein, respectively.

Uses: Active immunisation of individuals aged 2 months to 2 years for the prevention of invasive diseases caused by Hib and MenC.

Dosage and administration: Use in accordance with official recommendations. Primary vaccination of infants 2-12 months with 3 doses of 0.5ml given at least 1 month apart or infants 3-12 months with 2 doses given at least 2 months apart. Preterm infants born between 25 weeks and 36 weeks of gestational age : 3 primary doses, each of 0.5 ml, should be administered from 2 months up to 12 months of age with an interval of at least 2 months between doses. Single booster doses of Hib and MenC to be given between 12 months to 2 years of age (≥6m after last priming dose or ≥5 month after 2-dose priming course). Intramuscular injection only, preferably in the anterolateral thigh region. Menitorix should under NO circumstances be administered intravascularly, intradermally or subcutaneously.

Contraindications: Hypersensitivity to the active substances (including tetanus toxoid) or any of the excipients. Hypersensitivity reaction after previous administration of Menitorix. Acute severe febrile illness.

Special warnings and precautions: See SmPC for details. Appropriate medical treatment and supervision to be available in case of anaphylactic reaction. Precede with full medical history and examination. Caution in individuals with thrombocytopenia or any coagulation disorder. Only confers protection against Hib and MenC, may not completely protect. Duration of protection against MenC disease not known. No data on use in toddlers not primed or immunodeficient subjects – the latter may not achieve protective immunity. Individuals with complement deficiencies (e.g. on eculizumab) remain at increased risk of invasive MenC disease. Remain alert to coincidental meningitis. Risk of apnoea - consider respiratory monitoring in premature infants or those with history of respiratory immaturity, but do not delay immunisation. Not a substitute for tetanus immunisation. Hib capsular polysaccharide antigen is excreted in the urine – use other diagnostic test. Solvent contains <1mmol sodium (23mg) per dose.

Interactions: Do not mix with other vaccines in same syringe. Different vaccines to be administered at different injection sites. Concomitant administration with DTPa, HBV, IPV and Hib combination vaccines can result in lower antibody response – see SPC for details.

Adverse reactions: See SPC for full details. Very common: decreased appetite, irritability, drowsiness, fever (rectal ≥ 38°C), injection site reactions (swelling, pain, redness). Common: injection site reactions (including induration/nodule). Serious from post-marketing experience (frequency not known): allergic reactions, febrile seizures, hypotonia, apnoea in very premature infants. Post-marketing experience with other Meningococcal C vaccines (very rare): severe skin reactions, collapse or shock-like state (hypotonic-hyporesponsiveness episode), faints, seizures in patients with pre-existing seizure disorders, hypoaesthesia, paraesthesia, relapse of nephrotic syndrome, arthralgia, petechiae and/or purpura.

Legal category: POM. **Presentation and basic NHS cost:** Powder in a vial with a stopper (butyl rubber); 0.5ml of solvent in pre-filled syringe with a plunger stopper (butyl rubber); with or without separate needles: 1 = £37.76. **MA number:** PL 10592/0217. **MA holder:** SmithKline Beecham Ltd; Trading as: GlaxoSmithKline UK, 980 Great West Road, Brentford, Middlesex, TW8 9GS. **Further information is available from:** the GSK Customer Contact Centre: customercontactuk@gsk.com; Freephone 0800 221 441. Menitorix is a 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.