

Prescribing Information - Refer to SPC before prescribing.

MENITORIX® *Haemophilus influenzae* type b and *Meningococcal* group C conjugate vaccine. **Composition:** Each 0.5 ml dose contains 5µg *Haemophilus* type b 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 *Haemophilus influenzae* type b (Hib) and *Neisseria meningitidis* group C (MenC). **Dosage and administration:** 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, in accordance with official recommendations. After primary vaccination, booster doses of Hib and MenC must be administered. For special populations, see SPC. Intramuscular injection only; must not 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. **Precautions:** Caution in individuals with thrombocytopenia or any coagulation disorder. Menitorix will only confer protection against *Haemophilus influenzae* type b and *Neisseria meningitidis* group C. No data available on use of Menitorix in immunodeficient subjects. Individuals receiving treatment that inhibits terminal complement activation (for example, eculizumab) remain at increased risk of invasive disease caused by *Neisseria meningitidis*

group C, even following vaccination with Menitorix. For use in premature infants, see SPC. **Adverse reactions: Very common:** decreased appetite, irritability, drowsiness, fever (rectal $\geq 38^{\circ}\text{C}$), injection site reactions (swelling, pain, redness). **Common:** injection site reactions (including induration/nodule). From post-marketing experience (frequency not known): lymphadenopathy, allergic reactions, febrile seizures, hypotonia, apnoea in very premature infants. Postmarketing experience with other Meningococcal C vaccines (very rare): severe skin reactions, collapse or shock-like state (hypotonic-hyporesponsiveness episode), seizures in patients with pre-existing seizure disorders, hypoaesthesia, paraesthesia, relapse of nephrotic syndrome, arthralgia, petechiae and/or purpura. Please see SPC for full details. **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. NHS Cost 1 = £37.76. **MA number:** PL10592/0217. **MA holder:** SmithKline Beecham Ltd; Trading as: GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. **Further information is 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 or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline 0800 221 441