Prescribing information: See Summary of Product Characteristics before prescribing.

Bexsero Meningococcal group B Vaccine (rDNA, component, adsorbed), suspension for injection in pre-filled syringe. **Composition:** One (0.5 ml) dose contains: Recombinant *Neisseria meningitidis* group B NHBA fusion protein, recombinant *Neisseria meningitidis* group B NadA protein, recombinant *Neisseria meningitidis* group B fHbp fusion protein. Outer membrane vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254. **Indications:** Active immunisation of individuals from 2 months of age and older against invasive meningococcal disease caused by *Neisseria meningitidis* group B. **Dosage and Administration:** Primary immunisation: **Infants 2-5 months of age**: three doses each of 0.5 ml, not less than 1 month apart**. Infants 3-5 months of age**, two doses not less than 2 months apart. **Infants/children, 6-23 months of age:** two doses each of 0.5 ml, not less than 2 months apart. **Children, 2-10 years:** two doses each of 0.5 ml, not less than 1 month apart. **Adolescents from 11 years and adults:** two doses each of 0.5 ml, not less than 1 month apart. There are no data in adults above 50. **Refer to SPC for Booster doses.** The vaccine is given by deep intramuscular injection, preferably in the anterolateral aspect of the thigh in infants or in the deltoid muscle region of the upper arm in older subjects. The vaccine must not be injected intravenously, subcutaneously or intradermally and must not be mixed with other vaccines in the same syringe. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Precautions:** Postpone in subjects suffering from an acute severe febrile illness. Anxiety-related reactions e.g. syncope, hyperventilation or stress-related reactions may occur as a psychogenic response to the needle injection. Bexsero will not protect against all circulating meningococcal group B strains. Should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection unless the potential benefit clearly outweighs the risk of administration. A temperature elevation may occur following vaccination of infants and children (less than 2 years of age). Prophylactic antipyretics should be initiated according to local guidelines in infants and children (less than 2 years of age). Limited data in subjects with chronic medical conditions. Potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. Consider the benefit-risk prior to administering this vaccine to subjects with known history of hypersensitivity to latex. **Interactions:** Administer at separate injection sites when given concomitantly with other vaccines. Separate vaccinations can be considered when possible. **Fertility, Pregnancy and Lactation:** Insufficient clinical data on exposed pregnancies are available. The benefit-risk ratio should be considered when immunising breastfeeding women. There are no data on fertility in humans. **Adverse Reactions:** See SPC for full details. **Infants and children (up to 10 years of age),** *Very common (≥1/10)/common (≥1/100 to <1/10):* eating disorders, sleepiness, unusual crying, diarrhoea, headache, vomiting, rash, arthralgia, fever (≥38°C), injection site tenderness, injection site erythema, injection site swelling, injection site induration and irritability. *Uncommon (≥1/1,000 to <1/100):* seizures (including febrile seizures), eczema, pallor and fever (≥40°C). **Adolescents and Adults**: *Very common (≥1/10):* headache, nausea, myalgia, arthralgia, injection site pain, injection site swelling, injection site induration, injection site erythema and malaise. *Other important side effects for all age groups, frequency unknown:* allergic reactions (including anaphylactic reactions), hypotonic-hyporesponsive episode, injection site reactions (including extensive swelling of the vaccinated limb, blisters at or around the injection site and injection site nodule which may persist for more than one month). **Legal Category:** POM**. NHS List price:** £75 per dose **Marketing Authorisation Holder:** GSK Vaccines S.r.l., Via Fiorentina 1, 53100 Siena, Italy. **Marketing Authorisation Number:** EU/1/12/812/001 to 004. **The SPC and further information is available on request from:** Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441.

UK/BEX/0008/18 Date of preparation: June 2018

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