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12th February 2024

BEXSERO vaccine
Meningococcal Group B Vaccine (rDNA, component, adsorbed)
BEXSERO vaccine will be supplied as a single-dose in a UK pack

Dear Healthcare Professional,

This communication is intended for Healthcare Professionals who administer the BEXSERO vaccine to patients.

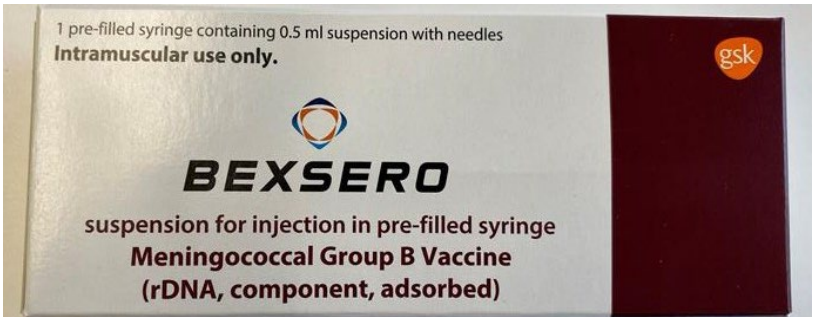
Summary
GSK is providing additional supply of BEXSERO vaccine with a UK pack and leaflet to the New Zealand market, upon request from PHARMAC to accommodate an increase in demand for the vaccine

Batch Number: ABXD63AA Expiry Date: 02/2027

General packaging differences
The UK pack contains two needles (needle 25GX5/8 TERUMO + needle 23G1 0,6X25MM), the NZ registered pack does not contain needles.

Carton differences
The classification and warning statements, the Statement 'Contains no antimicrobial preservative' and the New Zealand distribution information are not present on the UK pack.

New Zealand Packaging



UK Packaging

Leaflet
The leaflet included in the UK pack is an equivalent of the consumer medicine information (CMI) leaflet. The UK CMI leaflet and the NZ CMI are aligned for indication and dosing information.

BEXSERO is a prescription medicine. The New Zealand Data Sheet and Consumer Medicine Information for BEXSERO may be accessed at: www.medsafe.govt.nz

For further information about BEXSERO, please contact GSK Pharmaceutical Medical Information Department on 0800 808 500.

Yours Sincerely,

J Chapman

Jessica Chapman
Medical Affairs Manager
GSK New Zealand

BEXSERO (Multicomponent Meningococcal group B vaccine) is available as an injection for active immunisation against invasive disease caused by *N. meningitidi*s group B strains from 2 months of age. BEXSERO is a **prescription medicine**. From 1 March 2023, BEXSERO is funded as part of the National Immunisation Schedule for infants and children under 5, people aged 13-25 years in close-living situations, and for certain individuals considered at increased risk of meningococcal B. See Pharmaceutical Schedule for full funding criteria. BEXSERO is also available for private purchase – a prescription charge will apply. A single 0.5 mL dose contains 50 mcg of *Neisseria meningitidis* Group B Neisseria Heparin Binding Antigen fusion protein, 50 mcg of *Neisseria meningitidis* Group B Neisseria Adhesin A protein, 50 mcg of *Neisseria meningitidis* Group B Factor H Binding Protein fusion protein, 25 mcg of Outer membrane vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 (PorA P1.4). **Dosage and Administration: Deep intramuscular injection.** 0.5 mL dose in a pre-filled syringe. Infants (2-5 months): 2 doses (≥2 month interval), booster dose from 12 months (≥6 month interval between primary series and booster). Unvaccinated infants (6-11 months): 2 doses (≥2 month interval), booster dose from 12 months (≥2 month interval between primary series and booster). Unvaccinated toddlers (12-23 months): 2 doses (≥2 month interval), booster dose (12-23 month interval between primary series and booster). Children 2 years – adults 50 years: 2 doses (≥1 month interval), need for booster not established. When given concomitantly with other vaccines BEXSERO must be administered at separate injection sites. Prophylactic use of paracetamol (as per local guidelines) reduces the incidence and severity of fever without affecting the immunogenicity of BEXSERO. **Contraindications:** Hypersensitivity to any vaccine component. **Precautions: Do not administer intravenously, subcutaneously or intradermally.** This medicinal product must not be mixed with other vaccines in the same syringe. Ensure medical treatment is readily available in case of anaphylactic reactions following administration. Postpone vaccination during acute severe febrile illness. Prophylactic administration of antipyretics at the time of and closely after vaccination can reduce the incidence and intensity of post-vaccination febrile reactions. Antipyretic medication should be initiated according to local guidelines in infants and toddlers. Apnoea in very premature infants. Pregnancy: category B1. May contain latex and kanamycin. The safety and efficacy of BEXSERO in individuals above 50 years of age have not been established. As with any vaccine, vaccination with BEXSERO may not protect all vaccine recipients. BEXSERO is not expected to provide protection against all circulating meningococcal B strains. **Adverse reactions:** Infants, toddlers & children: eating disorders, sleepiness, unusual crying, headache, diarrhoea, vomiting, rash, fever (≥38°C), injection site reactions, irritability, arthralgia. Adolescents & Adults: headache, nausea, injection site reactions, malaise, myalgia, arthralgia. This is not a full list. **Before prescribing BEXSERO, please review the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects available at www.medsafe.govt.nz.** Marketed by GlaxoSmithKline NZ Ltd, Auckland.
Adverse events involving GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500. Date of Approval: **02 2024** Date of Expiry**: 02 2026** TAPS DA2351JC-NP-NZ-BEX-LTR-230002