

## Meningococcal B Vaccine (four component recombinant, adsorbed) BEXSERO®

Supplier: GlaxoSmithKline Inc.

### INDICATIONS: <sup>A</sup>

Provided free to:

- Individuals 2 months of age and older who are close contacts of a case of serogroup B invasive meningococcal disease who meet the public health criteria for immunoprophylaxis.
- In consultation with BCCDC, individuals 2 months of age and older who are at risk during IMD outbreaks caused by *N. meningitidis* serogroup B or the emergence of hyperendemic and/or hypervirulent *N. meningitidis* strains that are predicted to be susceptible to vaccine.

### RECOMMENDED BY THE NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION BUT NOT PROVIDED FREE IN BC:

- Medically high risk individuals 2 months of age and older with:
  - Functional or anatomical asplenia, including sickle cell disease
  - Congenital complement, properdin, factor D or primary antibody deficiencies
  - Acquired complement deficiencies due to receipt of the terminal complement inhibitor eculizumab (Soliris®) <sup>B</sup>
- Research, industrial and clinical laboratory personnel who are routinely exposed to *N. meningitidis* serogroup B
- Military personnel during recruit training and on certain deployments
- Travelers to an area with a hyperendemic strain or an outbreak that is known to be caused by *N. meningitidis* serotype B that can be prevented by vaccine.

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### DOSES AND SCHEDULE:

Infants 2-5 months of age (inclusive): 3 doses given as 0.5 mL **IM**, 4 weeks apart with a fourth dose after 12 months of age and at least 8 weeks after dose 3.

Infants 6-11 months of age (inclusive): 2 doses given as 0.5 mL **IM**, 8 weeks apart, with a third dose after 12 months of age and at least 8 weeks after dose 2.

Children 12 months-10 years of age (inclusive): 2 doses given as 0.5 mL **IM**, 8 weeks apart

Individuals 11 years of age and older: 2 doses given as 0.5 mL **IM**, 4 weeks apart.

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### ADMINISTRATION:

No additional requirements.

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<sup>A</sup> Bexsero® is approved for use in children 2 months to 17 years of age (inclusive), however based on expert opinion (as per the [Canadian Immunization Guide](#)), it may be administered to individuals 18 years of age and older.

<sup>B</sup> Individuals should be vaccinated with Bexsero® prior to initiating eculizumab (Soliris®). For those who are already being treated with eculizumab (Soliris®), refer to the [Health Canada alert](#) for more information.

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### **BOOSTER DOSES:**

No booster doses are recommended at this time.

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### **SEROLOGICAL TESTING:**

Serological testing is not recommended before or after immunization.

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### **CONTRAINDICATIONS:**

1. History of anaphylactic reaction to a previous dose of meningococcal B-containing vaccine, or to any component of Bexsero®.
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### **PRODUCT COMPONENTS:**

Potential allergens: kanamycin.

Other components: aluminum hydroxide, histidine, sucrose.

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### **PRECAUTIONS:**

The immunogenicity and safety of this vaccine in pregnant or lactating women, or in adults over 55 years of age has not been established however vaccination should not be withheld if indicated.

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### **SPECIAL CONSIDERATIONS:**

- Higher rates of fever have been observed with simultaneous administration of Bexsero® and routine infant vaccines; therefore, routine prophylactic administration of acetaminophen is recommended for infants and children up to three years of age when Bexsero® is given concurrently with other routine vaccines.
  - An increased risk of hemolysis or low hemoglobin has been observed when clients already being treated with eculizumab (Soliris®) were vaccinated with Bexsero®. For recommendations on vaccinating such clients, see the [Health Canada alert](#).
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### **ADVERSE EVENTS:**

#### **Infants and children:**

**Local:** tenderness, erythema, induration, swelling.

**Systemic:** fever, sleepiness, irritability, unusual crying. Higher proportion of systemic reactions, including temperature  $\geq 38^{\circ}\text{C}$ , when given together with other routine vaccines.

#### **Adolescents and adults:**

**Local:** pain, erythema, induration, swelling.

**Systemic:** malaise, headache, myalgia.

**Rare Reports of Kawasaki Disease** were identified in clinical trials however no causal relationship has been established.