Meningococcal B Multicomponent Recombinant Vaccine

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.279**	
Created and approved by	Provincial Immunization Program Standards and Quality		
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	Bexsero
Manufacturer	GlaxoSmithKline Inc.
Classification	Non-live: recombinant
Indications for Provincially Funded Vaccine	**Pre-exposure:**

Individuals 2 months of age and older:

- Individuals at high risk of invasive meningococcal disease (IMD) due to the following underlying medical conditions:
  - Asplenia – anatomical or functional (including sickle-cell disease).
  - Acquired complement deficiencies such as, due to receipt of the terminal complement inhibitor eculizumab (Soliris) or ravulizumab (Ultomiris).

    Note:
    - Individuals prescribed eculizumab (Soliris) or ravulizumab (Ultomiris) should receive meningococcal vaccine at least two weeks before receiving the first dose of eculizumab (Soliris) or ravulizumab (Ultomiris).
  - Congenital complement, properdin, factor D deficiency or primary antibody deficiencies.
  - Human immunodeficiency virus (HIV) infection.
- Laboratory workers routinely exposed to Neisseria meningitidis (N. meningitis), if they are involved in conducting subculture identification, susceptibility testing, serological and/or molecular characterization and deep freeze for storage. Laboratory workers performing only initial specimen plants are not eligible.
- Meningococcal disease outbreaks caused by serogroup B N. meningitidis or the emergence of hyperendemic and/or hypervirulent N. meningitidis strains that are predicted to be susceptible based on Meningococcal Antigen Typing System testing.

Note:

- Meningococcal vaccine is not routinely recommended for health care workers (HCWs). It is recommended that HCWs use barrier precautions to avoid direct contact with respiratory secretions from any patient.

Post-exposure:

- Individuals 2 months of age and older
- Identified household and close contacts of laboratory confirmed cases of meningococcal serogroup B IMD.

  Note: Results of index case serogroup should be confirmed (generally within 2 to 5 days) before proceeding with immunization.

For disease information, contact assessment and reporting guidelines refer to Alberta public health disease management guidelines: meningococcal disease, invasive.

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Schedule	**Pre-exposure:**
	2 months up to and including 5 months of age (3 doses): • Dose 1: 2 months of age • Dose 2: 4 months of age • Dose 3: 12 months of age or older with a minimum of 6 months from the second dose **Note:** • Interval between the dose 1 and dose 2 must be at least 8 weeks. If the interval between the first two doses is less than 8 weeks, a third dose should be given at least 4 weeks after dose 2 and a fourth dose in the second year of life with an interval of at least 6 months from dose 3. **6 months up to and including 11 months of age (3 doses):** • Dose 1: Day 0 • Dose 2: at least 8 weeks after dose 1 • Dose 3: 12 months of age or older with a minimum of at least 8 weeks after dose 2. **12 months of age up to and including 9 years of age (2 doses):** • Dose 1: Day 0 • Dose 2: at least 8 weeks after dose 1 **10 years of age and older (2 doses):** • Dose 1: Day 0 • Dose 2: at least 4 weeks after dose 1. **Booster doses:** recommended every 3 to 5 years for individuals who remain on eculizumab (Soliris) or ravulizumab (Ultomiris). • 6 years of age or younger at time of initial immunization: administer a booster dose 3 years after the last dose followed by a booster dose every 5 years. • 7 years of age and older at time of initial immunization: administer a booster dose every 5 years. ○ Individuals 7 years and older on complement inhibitors may receive a booster every 3 years at the request of the specialist involved in their care.
	Post exposure:
	Close contacts (as defined in the Alberta public health disease management guidelines: meningococcal disease, invasive) are recommended to receive post-exposure vaccine. **No previous Bexsero vaccine** **2 months up to and including 5 months of age (4 doses):** • Dose 1: as soon as possible after exposure • Dose 2: 4 weeks after dose 1 • Dose 3: 4 weeks after dose 2 • Dose 4: at 12 months of age or older, and at least 1 month after dose 3 **Note:** • it is preferred that the fourth dose be administered early in the second year of life. **6 months up to and including 11 months of age (3 doses):** • Dose 1: as soon as possible after exposure • Dose 2: 8 weeks after dose 1 • Dose 3: at 12 months of age and at least 8 weeks after dose 2. **12 months to up to and including 9 years of age (2 doses):**

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	• Dose 1: as soon as possible after exposure
	• Dose 2: 8 weeks after dose 1
	
	10 years of age and older (2 doses):
	• Dose 1: as soon as possible after exposure
	• Dose 2: 4 weeks after dose 1
	
	Previously immunized with Bexsero vaccine
	2 months of age and older
	• 1 dose post-exposure if:
	  ○ The last dose of vaccine was given prior to 1 year of age and more than 4 weeks has passed since their last dose; OR
	  ○ They have an underlying medical condition that puts them at risk for meningococcal group B disease and more than 4 weeks has passed since their last dose of vaccine; OR
	  ○ They have no underlying medical condition that puts them at risk for meningococcal group B disease, and the last dose of vaccine was given after 1 year of age and more than 1 year has passed since their last dose.
	• Comple immunization series following routine pre-exposure schedule if eligible and not already fully immunized.

Preferred Use	N/A
Dose	0.5 mL
Route	IM
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of the vaccine. • Anaphylactic or other allergic reactions to a previous dose of this vaccine or to a vaccine containing similar components. **Precautions:** • Protection against all circulating meningococcal serogroup B strains is not expected. • It is recommended that routine prophylactic acetaminophen be considered for preventing fever in infants and children up to 3 years of age. • Separating Bexsero vaccine from routine immunization schedules may be considered for preventing fever in children up to 3 years of age.

Possible Reactions	**Common:**
	• Injection site pain, tenderness, erythema, induration and swelling.
	• Infants and children less than 2 years of age: change to eating habits, vomiting, diarrhea, sleepiness, irritability, rash (urticarial), unusual crying, and fever.
	• Fever was more frequently reported following immunization with Bexsero administered simultaneously with routine vaccines.
	  ○ Children experiencing fever after preceding doses have a higher probability of developing fever after subsequent doses.
	  ○ Fever rates are lower with increasing age.
	• Children 2 years of age up to and including 10 years of age: change to eating habits, sleepiness, vomiting, diarrhea, irritability, headache, arthralgia, rash, fever.
	• Adolescents and adults: headache, malaise, myalgia, arthralgia, fever, nausea.
	
	Uncommon:
	• Infants and children (2 months of age to 10 years of age): urticaria, eczema, seizures (including febrile seizures), pallor.

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	Rare: • Infants and children (2 months of age to 10 years of age): Kawasaki syndrome. • Anaphylaxis. The following additional adverse events have been reported from post-marketing surveillance: blisters at or around the injection site, injection site nodule hypotonic-hyporesponsive episode.
Pregnancy	Consult with the MOH/designate. • There is not enough data available for use during pregnancy. • Not routinely recommended for people who are pregnant. • MOH/designate will make an individual recommendation based on risk of disease versus benefit of vaccine.
Lactation	May use for people who are lactating and feeding their milk to infants or children.
Composition	Each 0.5 mL dose of vaccine contains: • 50 mcg recombinant Neisseria meningitidis serogroup B NHBA (Neisseria Heparin Binding Antigen) fusion protein • 50 mcg recombinant Neisseria meningitidis serogroup B NadA (Neisseria adhesin A) protein • 50 mcg recombinant Neisseria meningitidis serogroup B fHbp (factor H binding protein) fusion protein • 25 mcg outer membrane vesicles (OMV) from Neisseria meningitidis serogroup B strain NZ98/254 measured as amount of total protein containing the PorA P1.4 • Produced in E. coli by recombinant DNA technology • 1.5 mg aluminum hydroxide • 3.125 mg sodium chloride • 0.776 mg histidine • 10 mg sucrose • Water for injection • Residue from manufacturing process: kanamycin. If present, levels are less than 0.01 mg per dose.
Blood/Blood Products	No blood products are used.
Bovine/Porcine Products	**Bovine Products:** • Deoxycholate from bovine bile is used as a raw material during the routine manufacturing process. **Porcine Products:** • None.
Latex	Tip cap of syringe may contain natural rubber latex.
Interchangeability	N/A
Administration with Other Products	May be given at the same time as other inactivated and live vaccines. • Use a separate needle and syringe for each vaccine. • The same limb may be used, if necessary, but use different sites on the limb. Recommend prophylactic acetaminophen for infants and children up to 3 years of age when other vaccines will be given.
Preparation	• Shake vaccine well before use to form a homogenous suspension
Appearance	• White opalescent liquid suspension • Fine off-white deposit may form when product stands for long period of time
Storage	• Store at +2°C to +8°C • Do not freeze

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	• Do not use beyond labeled expiry date • Store in original packaging to protect from light.
Vaccine Code	Men-B
Antigen Code	MENING-B
Licensed for	Individuals 2 months of age up to and including 25 years of age.
Off-License Use	Individuals 26 years of age and older as outlined in the Indications section.

Notes	• 2014 September 23: Meningococcal B Multicomponent Recombinant Vaccine Bexsero became available for post exposure immunization of individuals in Alberta identified as household or close contacts of laboratory confirmed cases of meningococcal serogroup B IMD.
	• 2015 February 25: Meningococcal B Multicomponent Recombinant Vaccine Bexsero became available for pre-exposure high risk individuals, outbreaks, and pre-exposure schedule depending on age.
	• 2022 March 15: Spacing updated from 8 weeks to 4 weeks between doses for individuals 2 years of age and older in pre-exposure schedule as per product monograph.
	• 2025 January 31:
	  ○ Added ravulizumab (Ultomiris) to complement inhibitors.
	  ○ Clarification that meningococcal vaccine is not routinely provided to health care workers.
	  ○ Updated booster dose recommendation for individuals 7 years and older on complement inhibitors.
	  ○ Updated schedules and minimum intervals between doses for select age groups.
	• 2025 Aug 01: Moved the statement routine prophylactic acetaminophen and separating Bexsero can be considered for preventing fever in infants and children up to 3 years of age to the precaution section.

Related Resources	Meningococcal B Vaccine Information Sheet

References

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