

Meningococcal B Multicomponent Recombinant Vaccine: Bexsero®

Revision Date: March 15, 2022

Rationale for Update:

- 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.

Please consult the Product Monograph ¹ for further information about the vaccine.	
	BEXSERO®
Manufacturer	GlaxoSmithKline Inc.
Licensed use	Individuals two months through 25 years of age. ¹
Off-license use	Individuals 26 years of age and older.
Indications for use of provincially funded vaccine	<p>Individuals 2 months of age and older:</p> <p>Pre-exposure:</p> <ul style="list-style-type: none"> Individuals at high risk of invasive meningococcal disease (IMD) due to underlying medical conditions as listed:^{2,3} <ul style="list-style-type: none"> ➤ Asplenia – anatomical or functional (including sickle-cell disease). ➤ Acquired complement deficiencies e.g., due to receipt of the terminal complement inhibitor eculizumab (Soliris®) <p>Note: Individuals prescribed eculizumab (Soliris®) should receive meningococcal vaccine at least two weeks before receiving the first dose of Soliris® if possible.⁴</p> ➤ Congenital complement, properdin, factor D deficiency or primary antibody deficiencies. ➤ HIV infection Research, industrial and clinical laboratory personnel routinely exposed to N. meningitidis. Includes only involved in conducting subculture identification, susceptibility testing, serological and/or molecular characterization and deep freeze for storage. Laboratory workers who do only initial specimen plants are not eligible.^{2,3} 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 (MATS) testing.^{2,3}

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	<p>Post-exposure:</p> <ul style="list-style-type: none"> Immunization of identified household and close contacts of laboratory-confirmed cases of meningococcal serogroup B invasive meningococcal disease (IMD).^{2,5} <p>Note: Results of index case serogroup should be known (generally within 2 to 5 days) before proceeding with immunization.</p> <p>For disease information, contact assessment and reporting guidelines refer to <i>Public Health Notifiable Disease Management Guidelines - Meningococcal Disease, Invasive</i> ⁵</p>
Dose	0.5 mL
Route	Intramuscular injection
Schedule	<p>Pre-exposure:</p> <p>2 months – 5 months of age:</p> <ul style="list-style-type: none"> ❖ Dose 1: 2 months of age ❖ Dose 2: 4 months of age ❖ Dose 3: 12 months of age or older with a minimum interval of at least 6 months from the second dose. <p>Note: Interval between the first two doses 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 the second dose and a fourth dose in the second year of life with an interval of at least six months from the third dose.¹</p> <p>6 months to 11 months of age:</p> <ul style="list-style-type: none"> ❖ Dose 1: Day 0 ❖ Dose 2: at least 8 weeks after first dose ❖ Dose 3: 12 months of age or older with a minimum interval of at least 8 weeks from the second dose. <p>12 months to 23 months of age:</p> <ul style="list-style-type: none"> ❖ Two doses with a minimum interval of at least 8 weeks between doses <p>2 years of age and older</p> <ul style="list-style-type: none"> ❖ Two doses with a minimum interval of at least 4 weeks between doses <p>Note: It is recommended that routine prophylactic acetaminophen be considered for preventing fever in infants and children up to three years of age.²</p> <p>Booster doses: recommended every 3 to 5 years for individuals who remain on eculizumab (Soliris®).²</p> <ul style="list-style-type: none"> ❖ Six years of age and younger at time of initial immunization: <i>administer a booster dose three years after the last dose followed by a booster dose every five years.</i>⁶ ❖ Seven years of age and older at time of initial immunization: <i>administer a booster dose every five years.</i>⁶ <p>Post-exposure: The following close contacts are recommended to receive post-exposure vaccine^{5,6}</p> <ul style="list-style-type: none"> Household contacts of the case Persons who share sleeping arrangements with the case

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	<ul style="list-style-type: none"> • Person who have direct nose or mouth contamination with oral or nasal secretions of a case (e.g. kissing on the mouth, shared cigarettes, sharing bottles) • Children and staff in contact with a case in child care or nursery school facilities <p><u>No previous Bexsero® vaccine</u></p> <p>2 months – 5 months of age (four doses):^{1,6}</p> <ul style="list-style-type: none"> ❖ Dose 1: as soon as possible after exposure ❖ Dose 2: 4 weeks after first dose ❖ Dose 3: 4 weeks after second dose ❖ Dose 4: at 12 months of age or older and at least one month after third dose <p>Note: It is preferred that the fourth dose be administered early in the second year of life.⁶</p> <p>6 months to less than 11 years of age (three doses):⁶</p> <ul style="list-style-type: none"> ❖ Dose 1: as soon as possible after exposure ❖ Dose 2: 8 weeks after first dose ❖ Dose 3: at 12 months of age or older and at least 8 weeks after second dose¹ <p>11 years of age and older (two doses):⁶</p> <ul style="list-style-type: none"> ❖ Dose 1: as soon as possible after exposure ❖ Dose 2: 4 weeks after first dose¹ <p><u>Previously immunized with Bexsero® vaccine⁶</u></p> <p>2 months of age and older</p> <ul style="list-style-type: none"> ❖ One dose post-exposure if:⁶ <ul style="list-style-type: none"> ○ The last dose of vaccine was given prior to one 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 one year has passed since their last dose. <p>Complete series as necessary.</p> <p>Notes:</p> <ul style="list-style-type: none"> • It is recommended that routine prophylactic acetaminophen and/or separating the vaccine from routine immunization schedules be considered for preventing fever in infants and children up to three years of age.²
Contraindications	<ul style="list-style-type: none"> • Known severe hypersensitivity to any component of the vaccine or its container. • Anaphylactic or other allergic reactions to a previous dose of the vaccine.
Precautions	Protection against all circulating meningococcal serogroup B strains is not expected. ¹
Possible reactions	See Product Monograph
Pregnancy	Insufficient clinical data on exposed pregnancies are available. ¹ However, when indicated, the vaccine should be administered. ¹

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Lactation	Breastfeeding women should receive vaccine if indicated.
Program Notes	<ul style="list-style-type: none"> • 2014-09-23 - Bexsero® for contacts of meningococcal B. • 2015-02-25 - Bexsero® - Indications: pre-exposure for specified high-risk individuals, outbreaks, and pre-exposure schedules depending on age. • 2022-03-15 - 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.

References

- ¹ GlaxoSmithKline Inc. (2021, May 6) Bexsero® Multicomponent meningococcal B vaccine (recombinant, adsorbed). *Product Monograph* https://pdf.hres.ca/dpd_pm/00060905.PDF.
- ² National Advisory Committee on Immunization (2014 April) Advice for the Use of Multicomponent Meningococcal Serogroup B vaccine. <https://www.canada.ca/en/public-health/services/publications/healthy-living/meningococcal-serogroup-b-vaccine-advice.html>
- ³ Alberta Advisory Committee on Immunization. (2014, October). Record of Decisions (unpublished).
- ⁴ Alexion Pharma (2018, August 20). PrSoliris® (eculizumab). *Product Monograph*.
- ⁵ Alberta Health. Meningococcal disease, invasive. In *Public Health Notifiable Disease Management Guidelines*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html
- ⁶ National Advisory Committee on Immunization. (2020). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html