

Meningococcal B Multicomponent Recombinant Vaccine Biological Page

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| Section 7: | Biological Product Information | Standard #: 07.279 |
| Created by: | Province-wide Immunization Program, Standards and Quality | |
| Approved by: | Province-wide Immunization Program, Standards and Quality | |
| Approval Date: | January 1, 2015 | Revised: May 4, 2022 |

| Bexsero® | |
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| Manufacturer | GlaxoSmithKline Inc. |
| Biological Classification | Multicomponent Recombinant, adsorbed. |
| Indications for 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 the following underlying medical conditions: <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.</p> ○ Congenital complement, properdin, factor D deficiency or primary antibody deficiencies. ○ HIV infection. • Research, industrial and clinical laboratory personnel routinely exposed to <i>N. meningitidis</i>. Includes only laboratory personnel 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. • Meningococcal disease outbreaks caused by serogroup B <i>N. meningitidis</i> or the emergence of hyperendemic and/or hypervirulent <i>N. meningitidis</i> strains that are predicted to be susceptible based on Meningococcal Antigen Typing System (MATS) testing. <p>Post-exposure:</p> <ul style="list-style-type: none"> • Identified household and close contacts of laboratory confirmed cases of meningococcal serogroup B invasive meningococcal disease (IMD) <p>Note: Results of index case serogroup should be confirmed (generally within 2 to 5 days) before proceeding with immunization</p> <p>For disease information, contact assessment and reporting guidelines refer to Public Health Notifiable Disease Management Guidelines - Meningococcal Disease, Invasive.</p> |
| Schedule | <p>Pre-exposure:</p> <ul style="list-style-type: none"> • 2 months up to and including 5 months of age (3 doses): <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 of 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</p> |

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| | <p>weeks after the second dose and a fourth dose in the second year of life with an interval of at least 6 months from the third dose.</p> <ul style="list-style-type: none"> • 6 months up to and including 11 months of age (3 doses): <ul style="list-style-type: none"> ○ 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 23 months of age (2 doses): <ul style="list-style-type: none"> ○ Dose 1: Day 0 ○ Dose 2: at least 8 weeks after dose 1 • 2 years of age and older (2 doses): <ul style="list-style-type: none"> ○ Dose 1: Day 0 ○ Dose 2: at least 4 weeks after dose 1 <p>Booster doses: recommended every 3 to 5 years for individuals who remain on eculizumab (Soliris®).</p> <ul style="list-style-type: none"> • 6 years of age or younger at time of initial immunization: administer a booster dose three years after the last dose followed by a booster dose every five years. • 7 years of age and older at time of initial immunization: administer a booster dose every five years. <p>Note: It is recommended that routine prophylactic acetaminophen be considered for preventing fever in infants and children up to three years of age.</p> |
| | <p>Post exposure: Close contacts (as defined in the Public Health Notifiable Disease Management Guidelines - Meningococcal Disease, Invasive) are recommended to receive post-exposure vaccine.</p> <p>No previous Bexsero® vaccine:</p> <ul style="list-style-type: none"> • 2 months up to and including 5 months of age (4 doses): <ul style="list-style-type: none"> ○ 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 least 12 months of age or older and at least 4 weeks after dose 3 <p>Note: The fourth dose should be administered early in the second year of life</p> • 6 months up to and including 10 years of age (3 doses): <ul style="list-style-type: none"> ○ 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 • 11 years of age and older (2 doses): <ul style="list-style-type: none"> ○ Dose 1: as soon as possible after exposure ○ Dose 2: 4 weeks after dose 1 <p>Previously immunized with Bexsero® vaccine:</p> <ul style="list-style-type: none"> • 2 months of age and older One dose post-exposure if: <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> |

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| | <p>Notes:</p> <ul style="list-style-type: none"> Routine prophylactic acetaminophen and /or separating Bexsero® vaccine from routine immunization schedules may be considered for preventing fever in children up to 3 years of age. |
| Preferred Use | N/A |
| Dose | 0.5 mL |
| Route | IM |
| Contraindications/ Precautions | <p>Contraindications:</p> <ul style="list-style-type: none"> 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. <p>Precautions:</p> <ul style="list-style-type: none"> Protection against all circulating meningococcal serogroup B strains is not expected. |
| Possible Reactions | <p>Common:</p> <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 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. <p>Uncommon:</p> <ul style="list-style-type: none"> Infants and children (2 months of age to 10 years of age): urticaria, eczema, seizures (including febrile seizures), pallor. <p>Rare:</p> <ul style="list-style-type: none"> Infants and children (2 months of age to 10 years of age): Kawasaki syndrome. Anaphylaxis. <p>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.</p> |
| Pregnancy | Adequate data is not available for the use of Men-B vaccine during pregnancy. However, in post exposure situations, the vaccine should be administered. |
| Lactation | Can be administered to eligible breastfeeding women |
| Composition | <p>Each 0.5 mL dose of vaccine contains:</p> <ul style="list-style-type: none"> 50 mcg recombinant <i>Neisseria meningitidis</i> serogroup B NHBA (Neisseria Heparin Binding Antigen) fusion protein. 50 mcg recombinant <i>Neisseria meningitidis</i> serogroup B NadA (Neisseria adhesin A) protein. 50 mcg recombinant <i>Neisseria meningitidis</i> serogroup B fHbp (factor H binding protein) fusion protein. 25 mcg outer membrane vesicles (OMV) from <i>Neisseria meningitidis</i> serogroup B strain NZ98/254 measured as amount of total protein containing the PorA P1.4. Produced in <i>E. coli</i> by recombinant DNA technology. |

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| | <ul style="list-style-type: none"> • Adsorbed on aluminum hydroxide. • NHBA (Neisserial Heparin Binding Antigen), NadA (<i>Neisseria adhesin A</i>), fHbp (factor H binding protein). • Sodium chloride. • Histidine. • Sucrose. • Water for injection. • Residue from manufacturing process: kanamycin. |
| Blood/Blood Products | No blood products are used. |
| Bovine/Porcine Products | Bovine and porcine products are used as raw materials during the manufacturing process. |
| Latex | Tip cap of syringe may contain natural rubber latex. |
| Interchangeability | N/A |
| Administration with Other Products | Prophylactic acetaminophen should only be recommended for infants and children up to 3 years of age when other vaccines will be given. |
| Appearance | <ul style="list-style-type: none"> • White opalescent liquid suspension • Fine off-white deposit may form when product stands for long period of time • Shake vaccine well before use to form a homogenous suspension • Pre-filled syringe |
| Storage | <ul style="list-style-type: none"> • Store at +2°C to +8°C • Do not freeze • Do not use beyond labeled expiry date • Store in original packaging when possible to protect from light |
| Vaccine Code | Men-B |
| Antigen Code | MENING-B |
| Licensed Use | <ul style="list-style-type: none"> • Individuals 2 months of age up to and including 25 years of age. |
| Off-License Use | <ul style="list-style-type: none"> • Individuals 26 years of age and older as outlined in the Indications section. |
| Program Notes: | |
| <ul style="list-style-type: none"> • 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 invasive meningococcal disease. • 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. | |
| Related Documents: | |
| <ul style="list-style-type: none"> • Meningococcal B Vaccine Information Sheet | |
| References: | |
| <ol style="list-style-type: none"> 1. Alberta Advisory Committee on Immunization. (2014 October). Record of Decisions (unpublished). 2. Alberta Health, Health System Accountability and Performance Division, Alberta Immunization Policy (2022 March 15). <i>Meningococcal B Vaccine: Bexsero®</i>. 3. Alberta Health. Meningococcal disease, invasive. In <i>Public Health Notifiable Disease Management Guidelines</i>. https://www.alberta.ca/notifiable-disease-guidelines.aspx 4. Alexion Pharma (2018 August 20). PrSoliris® (eculizumab). <i>Product Monograph</i>. | |

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| 5. | GlaxoSmithKline Inc. (2021 May 6) Bexsero® Multicomponent meningococcal B vaccine (recombinant, adsorbed). <i>Product Monograph</i> . https://pdf.hres.ca/dpd_pm/00060905.PDF |
| 6. | 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 |
| 7. | National Advisory Committee on Immunization. (2020). <i>Canadian Immunization Guide</i> (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html |