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 Monograph¹ for further information about the vaccine.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>GlaxoSmithKline Inc.</th>
</tr>
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<tbody>
<tr>
<td>Licensed use</td>
<td>Individuals two months through 25 years of age.¹</td>
</tr>
<tr>
<td>Off-license use</td>
<td>Individuals 26 years of age and older.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Indications for use of provincially funded vaccine</th>
<th>Individuals 2 months of age and older: Pre-exposure:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>- Individuals at high risk of invasive meningococcal disease (IMD) due to underlying medical conditions as listed:²,³</td>
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<td></td>
<td>- Asplenia – anatomical or functional (including sickle-cell disease).</td>
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<td>- Acquired complement deficiencies e.g., due to receipt of the terminal complement inhibitor eculizumab (Soliris®)</td>
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<td>Note: Individuals prescribed eculizumab (Soliris®) should receive meningococcal vaccine at least two weeks before receiving the first dose of Soliris® if possible.⁴</td>
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<td>- Congenital complement, properdin, factor D deficiency or primary antibody deficiencies.</td>
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<td>- HIV infection</td>
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<td></td>
<td>- 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</td>
</tr>
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<td></td>
<td>- 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</td>
</tr>
</tbody>
</table>

¹ Please consult the Product Monograph for further information on administration and contraindications.
² See the Meningococcal Antigen Typing System (MATS) testing for susceptibility information.
³ See the manufacturer’s product monograph for further information.
⁴ Individuals prescribed eculizumab (Soliris®) should receive meningococcal vaccine at least two weeks before receiving the first dose of Soliris® if possible.
⁵ See the manufacturer’s product monograph for further information.
**Post-exposure:**
- Immunization of identified household and close contacts of laboratory-confirmed cases of meningococcal serogroup B invasive meningococcal disease (IMD).\(^2\),\(^5\)

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

For disease information, contact assessment and reporting guidelines refer to *Public Health Notifiable Disease Management Guidelines - Meningococcal Disease, Invasive*\(^5\)

<table>
<thead>
<tr>
<th>Dose</th>
<th>0.5 mL</th>
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<tr>
<td>Route</td>
<td>Intramuscular injection</td>
</tr>
</tbody>
</table>

**Schedule**

**Pre-exposure:**

- **2 months – 5 months of age:**
  - 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.

**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.\(^1\)

- **6 months to 11 months of age:**
  - 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.

- **12 months to 23 months of age:**
  - Two doses with a minimum interval of at least 8 weeks between doses

- **2 years of age and older**
  - Two doses with a minimum interval of at least 4 weeks between doses

**Note:** It is recommended that routine prophylactic acetaminophen be considered for preventing fever in infants and children up to three years of age.\(^2\)

**Booster doses:** recommended every 3 to 5 years for individuals who remain on eculizumab (Soliris®).\(^2\)

- Six years of age and younger at time of initial immunization: *administer a booster dose three years after the last dose followed by a booster dose every five years.*\(^6\)
- Seven years of age and older at time of initial immunization: *administer a booster dose every five years.*\(^6\)

**Post-exposure:** The following close contacts are recommended to receive post-exposure vaccine\(^5,6\)

- Household contacts of the case
- Persons who share sleeping arrangements with the case
• 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

No previous Bexsero® vaccine

2 months – 5 months of age (four doses):¹,⁶
  ❖ 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

Note: It is preferred that the fourth dose be administered early in the second year of life.⁹

6 months to less than 11 years of age (three doses):⁶
  ❖ 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

11 years of age and older (two doses):⁶
  ❖ Dose 1: as soon as possible after exposure
  ❖ Dose 2: 4 weeks after first dose¹

Previously immunized with Bexsero® vaccine⁶

2 months of age and older
  ❖ One dose post-exposure if:⁶
    ○ 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.

Complete series as necessary.

Notes:
• 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
• 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 date on exposed pregnancies are available.¹ However, when indicated, the vaccine should be administered.¹
Lactation

Breastfeeding women should receive vaccine if indicated.

Program Notes

- 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

4 Alexion Pharma (2018, August 20). 