Meningococcal B Multicomponent Recombinant Vaccine: BEXSERO®

Revision Date: August 8, 2017

Please consult the Product Monograph[1] for further information about the vaccine.

	BEXSERO®
Manufacturer	Novartis Vaccines and Diagnostics Inc. - distributed by Novartis Pharmaceuticals Canada Inc.
Licensed use	Individuals two months through 17 years of age.
Off-license use	Individuals 18 years of age and older.
Indications for use of provincially funded vaccine	**Individuals 2 months of age and older:** **Pre-exposure:** Individuals at high risk of invasive meningococcal disease (IMD) due to underlying medical conditions as listed:[2,3] ➢ Asplenia – anatomical or functional (including sickle-cell disease). ➢ Acquired complement deficiencies e.g., due to receipt of the terminal complement inhibitor eculizumab (Soliris®) **Note**: Individuals prescribed eculizumab (Soliris®) should receive meningococcal vaccine at least two weeks before receiving the first dose of Soliris®[4] if possible. ➢ 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] **Post-exposure:** • Immunization of identified household and close contacts of laboratory-confirmed cases of meningococcal serogroup B invasive meningococcal disease (IMD).[2,4] **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*[4]
Dose	0.5 mL

Route	Intramuscular injection
Schedule	**Pre-exposure:** **2 months – 5 months of age:** ❖ Dose 1: 2 months of age ❖ Dose 2: 4 months of age ❖ Dose 3: 6 months of age ❖ Dose 4: 12 months of age **Note:** Interval between doses may be shortened to one month but 4th dose must be administered at 12 months of age or older.[2] **6 months – 11 months of age:** ❖ Doses 1 and 2 at least two months apart ❖ Dose 3 after 12 months of age and with minimal interval of at least eight weeks from 2nd dose. **12 months – 10 years of age:** ❖ Two doses with a minimal interval of at least two months between doses **11 years of age and older:** ❖ Two doses with a minimal interval of at least one month 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] **Post-exposure:** **2 months – 5 months of age (four doses):[1]** ❖ Dose 1: as soon as possible after exposure ❖ Dose 2: one month after dose 1 ❖ Dose 3: one month after dose 2 ❖ Dose 4: at 12 months of age or older and at least one month after dose 3 **Note:** It is preferred that the fourth dose be administered early in the second year of life.[1] **6 months – 11 months of age (three doses):[1]** ❖ Dose 1: as soon as possible after exposure ❖ Dose 2: two months after dose 1 ❖ Dose 3: at 12 months of age or older and at least two months after dose 2[1] **12 months – 10 years of age (two doses):[1]** ❖ Dose 1: as soon as possible after exposure ❖ Dose 2: two months after dose 1[1] **11 years of age and older (two doses):[1,2]** ❖ Dose 1: as soon as possible after exposure ❖ Dose 2: one month after dose 1[1] **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] • The need for booster doses following the administration of the above schedules has not been established.[1]

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	Most reactions were of a mild to moderate nature and resolved within 48 hours after immunization.[1] **Local reactions:** • Injection-site pain, tenderness, erythema, induration and swelling.[1] **Systemic reactions**: • Infants and children (less than 2 years of age): ➢ The most frequent reactions include irritability, fever, unusual crying, changes in appetite, sleepiness, rash, and vomiting/diarrhea. Uncommon reactions could include urticaria, eczema, seizures (including febrile seizures), pallor and rarely Kawasaki syndrome.[1] ➢ Fever was more frequently reported following immunization with BEXSERO® administered simultaneously with routine vaccines.[1] Children experiencing fever after preceding doses have a higher probability of developing fever after subsequent doses.[1] Fever rates were lower with increasing age.[1] • Adolescents and adults: headache, malaise, myalgia, arthralgia, fever, nausea.[1] • The following additional adverse events have been reported from post-marketing surveillance: Injection site reactions (including extensive swelling of the vaccinated limb, blisters at or around the injection site and injection site nodule which may persist for more than one month) and hypotonic-hyporesponsive episode. [1]. Refer to: *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*.[5]
Pregnancy	Insufficient clinical date on exposed pregnancies are available.[1] However, when indicated, the vaccine should be administered.
Lactation	Breastfeeding women should receive vaccine if indicated.

References

[1] Novartis Vaccines and Diagnostics Inc. and Novartis Pharmaceuticals Canada Inc. (2017, June 8). BEXSERO®: Multicomponent meningococcal B vaccine (recombinant, adsorbed). *Product Monograph*.

[2] Meningococcal B Pilot Project Task Group. (2014). The recommended use of the multicomponent meningococcal B (4CMenB) Vaccine in Canada: common guidance statement. Pan-Canadian Public Health Network. Retrieved June 5, 2014 from www.phac-aspc.gc.ca/naci-ccni/mening-4cmenb-exec-resum-eng.php

[3] Alberta Advisory Committee on Immunization. (2014, October). Record of Decisions (unpublished).

[4] Alexion Pharma International Sàrl. (2013-05-31). 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] Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.* www.health.alberta.ca/documents/AIP-Adverse-Events-Following-Immunization-Policy.pdf

