BEXSERO®

Multicomponent Meningococcal B Vaccine (recombinant, adsorbed)

The first vaccine for active immunization against MenB[1,2*]

BEXSERO® is indicated for active immunization of individuals from 2 months through 17 years old against invasive disease caused by *Neisseria meningitidis* serogroup B strains.

As with any vaccine, BEXSERO® may not protect all vaccine recipients. BEXSERO® is not expected to provide protection against all circulating meningococcal serogroup B strains.

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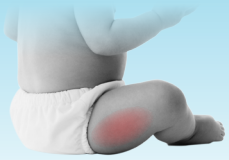
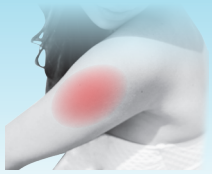
B vaccinated.

Recommended dosing schedule[1]

Age group	Primary immunization: Number of doses (0.5 mL)	Primary immunization: Time between doses	Booster (0.5 mL)
Infants 2 to 5 months	3 doses	≥1 month†	**1 dose** required in the second year of life between 12 and 23 months of age.‡
Unvaccinated infants 6 to 11 months	2 doses	≥2 months	**1 dose** required in the second year of life with an interval of ≥2 months between the second and third dose. The need for further booster doses has not been established.
Children 12 months to 10 years§	2 doses	≥2 months	**The need for booster dose has not been established.**
Adolescents 11 to 17 years	2 doses	≥1 month	**The need for booster dose has not been established.**

* MenB: meningococcal disease caused by serogroup B.
† The primary series consists of three doses, given at 2, 4 and 6 months of age. It can also be given at 2, 3 and 4 months of age, but the immune response to the NHBA antigen is lower.
‡ It is preferred this dose be given early in the second year of life, whenever possible.
§ The 12 months to 10 years of age population includes unvaccinated children aged 12 months through 23 months.

Recommended injection site[1]

Age group	Injection site
Infants 2 to 11 months	 Anterolateral aspect of thigh
Children and adolescents 12 months to 17 years	 Non-dominant deltoid muscle region of upper arm

BEXSERO® should be given by deep intramuscular injection. It must not be injected intravenously, subcutaneously, or intradermally; and must not be mixed with other vaccines in the same syringe.

Flexible options of co-administration with other vaccines[1]

BEXSERO® can be given concomitantly with any of the following vaccine antigens (either as monovalent or as combination vaccines)[1]:

- diphtheria
- tetanus
- acellular pertussis
- *Haemophilus influenzae* type b
- inactivated poliomyelitis
- hepatitis B
- heptavalent pneumococcal conjugate
- measles
- mumps
- rubella
- varicella

As higher percentages of subjects reported systemic reactions, including fever, change in eating habits, tenderness at the injection site and irritability, following BEXSERO® given concomitantly with routine vaccines than after BEXSERO® alone, separate vaccinations can be considered when possible. Prophylactic use of acetaminophen reduces the incidence and severity of fever without affecting the immunogenicity of either BEXSERO® or most antigens of routine vaccines. The effect of antipyretics other than acetaminophen on the immune response has not been studied.

Concomitant administration of BEXSERO® with vaccines other than those mentioned above has not been studied.

When given concomitantly with other vaccines, BEXSERO® should be administered at different injection site.

BEXSERO® must not be mixed with other medicinal products or other vaccines in the same syringe.

Indications and clinical use:

BEXSERO® is indicated for active immunization of individuals from 2 months through 17 years old against invasive disease caused by *N. meningitidis* serogroup B strains.

As the expression of antigens included in the vaccine is epidemiologically variable in circulating B strains, meningococci that express them at sufficient levels are predicted to be susceptible to killing by vaccine-elicited antibodies.

Contraindications:

- BEXSERO® should not be administered to individuals with hypersensitivity to this vaccine or to any ingredient in the formulation or components of the container closure.

Relevant warnings and precautions:

- The vaccine is not expected to provide protection against all circulating strains of meningococcal serogroup B strains
- Protection against invasive meningococcal disease caused by serogroups other than serogroup B should not be assumed
- As with any vaccine, BEXSERO® may not fully protect all vaccine recipients
- As with any vaccine, anxiety-related reactions may occur in association with vaccination as a psychogenic response to the needle injection
- Administration of BEXSERO® should be postponed in subjects suffering from an acute severe febrile illness
- Temperature elevation may occur following vaccination of infants and children (less than 2 years of age). Antipyretic treatment can be initiated according to local treatment guidelines
- Availability of appropriate medical treatment and supervision in case of an anaphylactic event following administration of the vaccine
- Risk of apnea in premature infants; consider respiratory monitoring for 48 – 72 hours
- Caution in subjects with known hypersensitivity to latex
- Vaccine use in kanamycin-sensitive recipients has not been established
- Individuals with thrombocytopenia, hemophilia or any coagulation disorder that would contraindicate intramuscular injection
- The expected immune response may not be obtained after vaccination of immunosuppressed patients

Adverse events:

The most frequent local and systemic adverse reactions after vaccination with BEXSERO® observed in clinical trials were:

Infants and children (less than 2 years of age):
- local reactions – tenderness, erythema, induration, pain, swelling
- systemic reactions – change in eating habits, fever ≥38°C, irritability, unusual crying, sleepiness, vomiting, diarrhea, rash

Children (aged 2 years through 10 years)
- local reactions – pain, tenderness, erythema, induration, swelling
- systemic reactions – change in eating habits, sleepiness, diarrhea, irritability, unusual crying, arthralgia, vomiting, headache, rash, fever ≥38°C

Adolescents and adults (11 years or older):
- local reactions – pain, erythema, induration
- systemic reactions – malaise, headache, muscle and joint pain, nausea, myalgia

Recommended dose and dosage adjustment:

Infants aged 2 months through 5 months:

The recommended immunization series consists of four doses. The primary infant series consists of three doses, given at 2, 4 and 6 months of age, followed by a fourth dose (booster).

The primary series can also be given at 2, 3 and 4 months of age, but the immune response to the NHBA antigen is lower.

With both schedules, a fourth dose (booster) is required in the second year of life between 12 and 23 months of age. It is preferred this dose be given early in the second year of life, whenever possible.

Unvaccinated infants aged 6 months through 11 months:

The vaccination schedule consists of three doses, with an interval of at least 2 months between the first and second dose. A third dose is required in the second year of life with an interval of at least 2 months between the second and third dose. The need for further booster doses has not been established.

Unvaccinated children aged 12 months through 10 years:

The vaccination schedule consists of two doses, with an interval of at least 2 months between doses. The need for a booster dose after this vaccination schedule has not been established.

Individuals aged 11 years through 17 years:

The vaccination schedule consists of two doses, with an interval of at least 1 month between doses. The need for a subsequent dose after this vaccination schedule has not been established.

Administration:

BEXSERO® should be given by deep intramuscular injection, preferably in the anterolateral aspect of the thigh in infants or in the non-dominant deltoid muscle region of the upper arm in older subjects.

Separate injection sites must be used if more than one vaccine is administered at the same time.

The vaccine must not be injected intravenously, subcutaneously or intradermally and must not be mixed with other vaccines in the same syringe.

BEXSERO® must not be mixed with other medicinal products.

For more information:

Please consult the Product Monograph at gsk.ca/bexsero/pm for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling Medical Information at 1-800-387-7374.

To report an adverse event, please call 1-800-387-7374.

If you have questions about BEXSERO®, please call 1-800-387-7374 or visit Health.GSK.ca

References: 1. BEXSERO® Product Monograph. October 11, 2016. 2. An Advisory Committee Statement (ACS), National Advisory Committee on Immunization (NACI). Advice for the use of the Multicomponent Meningococcal Serogroup B (4CMenB) Vaccine. April 2014. Available at http://publications.gc.ca/collections/collection_2014/aspc-phac/HP40-104-2014-eng.pdf.

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