**Protocol for Meningococcal Group B Vaccine (MenB)
BEXSERO®**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunizations.

**Vaccine Information Statements**

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at <http://www.immunize.org/vis>.

**FDA Approved Indications and Usage (See Package Insert, current version dated (09/2016)**

* **BEXSERO**® is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B.
* **BEXSERO**® is approved for use in persons aged 10 through 25 years.

**ACIP Recommended Use of MenB Vaccines (Note that some of these recommendations differ from the package inserts)**

* High-Risk (See “Eligible Groups” on page 3):
	+ **BEXSERO**® is recommended routinely for use in persons aged 10 through 25 years
	at increased risk for meningococcal disease attributable to serogroup B.
	+ **BEXSERO**® is recommended routinely for use in persons aged 26 years or older at increased risk for meningococcal disease attributable to serogroup B.
* Other than High-Risk (See “Eligible Groups” on page 3):
	+ **BEXSERO**® may be administered to adolescents aged 16 through 18 years to provide short-term protection against most strains of serogroup B meningococcal disease.
	+ **BEXSERO**® may be administered to young adults aged 19 through 23 years to provide short-term protection against most strains of serogroup B meningococcal disease.
* No preference is stated for the use of either of the two currently licensed MenB vaccines, **BEXSERO**® (MenB-4C) or TRUMENBA® (MenB-FHbp).
* Because the two MenB vaccines are antigenically different, **the same vaccine product must be used for all doses**.
* **BEXSERO**® is a 2-dose series and TRUMENBA® is either a 2-dose or a 3-dose series. The 2-dose TRUMENBA series can be used for routine vaccination of healthy persons (i.e., other than high-risk) aged 16 through 23 years.

**ACIP Recommended Schedule**

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| --- | --- | --- | --- |
| **Age Group** | **MenB Vaccine** | **Routine Recommendations** | **Dosing Schedule** |
| 10 through 18 Years  | **BEXSERO**®, Novartis | High-Risk only | Give two doses, at least one month apart (0 and 1-6 month schedule) |
| 19 Years or Older | **BEXSERO**®, Novartis | High-Risk only | Give two doses, at least one month apart (0 and 1-6 month schedule) |
| 10 through 18 Years | TRUMENBA®, Pfizer | High-Risk only | Give three doses (0, 2, and 6 month schedule) |
| 19 Years or Older | TRUMENBA®, Pfizer | High-Risk only | Give three doses (0, 2, and 6 month schedule) |

Note: "Both MenB vaccines are approved for use in persons aged 10 through 25 years; however, because there are no theoretical differences in safety for persons aged >25 years compared with those aged 10 through 25 years, ACIP supported routine use of MenB vaccines in persons aged ≥ 10 years who are at increased risk for serogroup B meningococcal disease."

Note: Use of MenB vaccines in persons aged 26 years or older would be an off-label use.

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| --- | --- | --- | --- |
| **Age Group** | **MenB Vaccine** | **Permissive Recommendations** | **Dosing Schedule** |
| 16 through 18 Years | **BEXSERO**®, Novartis | Other than High-Risk | Give two doses, at least one month apart (0 and 1-6 month schedule) |
| 19 through 23 Years | **BEXSERO**®, Novartis | Other than High-Risk | Give two doses, at least one month apart (0 and 1-6 month schedule) |
| 16 through 18 Years | TRUMENBA®, Pfizer | Other than High-Risk | Give two doses (0, and 6 month schedule) |
| 19 through 23 Years | TRUMENBA®, Pfizer | Other than High-Risk | Give two doses (0, and 6 month schedule) |

Note: ACIP recommended in October 2015 that a MenB vaccine series may be administered to adolescents and young adults aged 16 through 23 years to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16 through 18 years, [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm?s\_cid=mm6441a3\_w#tab1](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm?s_cid=mm6441a3_w#tab1)

**Eligible Groups**

* High-Risk: Children and adults aged 10 years and older, at increased risk for meningococcal disease attributable to serogroup B, including:
* Persons with persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D or taking eculizumab [Soliris®]).
* Persons with anatomic or functional asplenia, including sickle cell disease
* Microbiologists who routinely work with *Neisseria meningitidis* isolates in a laboratory.
* Persons identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup B.
* Other than High-Risk: Adolescents and young adults aged 16 through 23 years without high-risk conditions may be vaccinated, with a preferred age of vaccination at 16 through 18 years.

**Dosage and Route** (Always check the package insert prior to administration.)

* Administer two doses (0.5 mL each) of **BEXSERO**® at least 1 month apart on a
0 and 1-6 month schedule.
* For intramuscular injection in the deltoid muscle of the upper arm only.
* A dose of MenB vaccine and a dose of MenACWY vaccine may be administered at the same visit, but at a different anatomic site, or at any time before or after the other.

**Contraindications**

* Hypersensitivity, including severe allergic reaction, to any component of the vaccine or after a previous dose of **BEXSERO**®.

**Warnings and Precautions:**

* The tip caps of the pre-filled syringes contain natural rubber latex, which may cause allergic reactions in latex sensitive individuals.
* Syncope (fainting) can occur in association with administration of **BEXSERO**®.
* **BEXSERO**® may not protect all vaccine recipients.
* **BEXSERO**® may not provide protection against all meningococcal serogroup B strains.
* Individuals with altered immunocompetence may have reduced immune response to **BEXSERO**®.

**Adverse Events:**

* See product’s package insert.

**Use in Specific Populations**

* **BEXSERO**® should be used during pregnancy only if clearly needed. A Pregnancy registry is available for women who receive **BEXSERO**® during pregnancy. Contact Novartis Vaccines and Diagnostics at 1-877-683-4732.
* Caution should be exercised when **BEXSERO**® is administered to a nursing woman.
* Safety and effectiveness of **BEXSERO**® have not been established in children younger than 10 years of age.
* Safety and effectiveness of **BEXSERO**® have not been established in adults older than 65 years of age.
* **BEXSERO**® is not currently recommended for persons who travel to or reside in countries where meningococcal disease is hyperendemic or epidemic because the risk for meningococcal disease in these countries generally is not caused by serogroup B.

**Storage and Handling:**

* Do not freeze. Discard if the vaccine has been frozen.
* Store refrigerated, at 36°F to 46°F (2°C to 8°C).
* Protect from light
* Do not use after the expiration date.

**Patient Counseling Information:**

Prior to administration of this vaccine, the healthcare professional should inform the individual, parent, guardian, or other responsible adult about:

* The importance of completing the 2-dose immunization series with the same
MenB vaccine brand.
* Report any suspected adverse reactions to a healthcare professional.
* Individuals with altered immunocompetence may have reduced immune responses to **BEXSERO**®.
* Register women who receive **BEXSERO**® while pregnant in the pregnancy registry by calling 1-877-683-4732.

**References:**

Advisory Committee on Immunization Practices, Vaccines for Children Program, Vaccine to Prevent Meningococcal Disease. Resolution No. 10/16-3:

[http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2016-10-3-mening.pdf](http://www.immunize.org/catg.d/p3085.pdf)

Immunization Action Coalition (IAC): Needle Tips; ACIP Votes to Update Recommendations for HPV, Tdap, MenB and HepB Vaccines; Vol. 26-Number 4: December 2016.

http://www.immunize.org

Folaranmi T, Rubin L, Martin SW, et al. Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥10 Years at Increased Risk for Serogroup B Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices 2015.
MMWR Morb Mortal Wkly Rep 2015;64:608-612, [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6422a3.htm?s\_cid=mm6422a3\_e](http://www.cdc.gov/hepatitis?s_cid=mm6422a3_e)

MacNeil JR, Rubin L, Folaranmi T, et al. Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015. MMWR Morb Mortal Wkly Rep 2015;64:1171-1176.
[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm?s\_cid=mm6441a3\_w](https://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf?s_cid=mm6441a3_w)

Advisory Committee on Immunization Practices, Vaccines for Children Program, Vaccines to Prevent Meningococcal Disease. Resolution No. 6/15.1:

[http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2015-06-15-mening.pdf](http://chfs.ky.gov/dph/CCSG_Forms.htm).

Immunize.org. Vaccine Information Sheet: [http://www.immunize.org/vis/meningococcal\_b.pdf](https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf)

**BEXSERO**® Package Insert: Rev. 09/2016 [http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM431447.pdf](http://www.lrc.ky.gov/kar/902/002/020.htm) or <https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Bexsero/pdf/BEXSERO.PDF>

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