Meningococcal Group B Vaccine

AHFS Class: 80:12 — Vaccines (tofc-80)

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Alert:

On January 5, 2026, the US Department of Health and Human Services (HHS) announced the approval of a revised US childhood and adolescent immunization schedule (https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html (https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html)). Under the revised recommendations, CDC continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) but changes individual vaccine placement within those categories. For additional information, see https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html (https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html) .

Introduction

Meningococcal group B (MenB) vaccine is an inactivated (recombinant) vaccine that contains antigens derived from *Neisseria meningitidis* serogroup B.[1,2]

Uses

▪ Prevention of Meningococcal Group B Infection

Meningococcal group B (MenB) vaccine is used to stimulate active immunity to infection caused by *Neisseria meningitidis* serogroup B in adults, adolescents, and children 10–25 years of age.[1,2] MenB vaccine is also recommended in certain **adults 26 years of age or older [off-label]**† at increased risk for meningococcal infection caused by *N. meningitidis* serogroup B.[4,200] There are currently 2 preparations of the MenB vaccine in the US, MenB-4C (Bexsero®) and MenB-FHbp (Trumenba®).[1,2] MenB-4C (Bexsero®) contains 3 recombinant cell surface proteins (neisserial adhesin A [NadA], neisserial heparin-binding antigen [NHBA], factor H-binding protein [FHbp]) and outer membrane vesicles (OMV) containing outer membrane protein PorA (serosubtype P1.4) derived from *N. meningitidis* serogroup B.[1,15] MenB-FHbp (Trumenba®) contains 2 FHbp variants, one from FHbp subfamily A (A05) and one from FHbp subfamily B (B01), derived from *N. meningitidis* serogroup B.[2]

N. meningitidis can cause invasive meningococcal disease that usually presents as acute, severe, and potentially life-threatening meningitis and/or meningococcemia with abrupt onset.[105,166,300] Less frequently, *N. meningitidis* infection results in pneumonia and focal disease (e.g., septic arthritis).[105,166] Based on chemical differences in the antigenic capsular polysaccharide, 12 different serogroups of *N. meningitidis* have been identified.[105,166,300] In the US, serogroups B, C, and Y cause most cases of meningococcal disease; serogroup W and nongroupable strains cause a small percentage of cases.[105,166,237] Serogroup B causes approximately 60% of cases of meningococcal disease reported in the US in children and young adults <24 years of age.[166] The proportion of cases caused by each serogroup has changed over time anc varies based on geographic location and age group.[105,166] Although the overall incidence of meningococcal disease in the US has been historically low during the last 10–15 years,[3,105,166] the overall case fatality rate for invasive meningococcal disease has remained at 10–15%, even with anti-infective treatment.[105,166] In addition, long-term sequelae (e.g., hearing loss, neurologic disability, digit or limb amputations) have been reported in 10–20% of patients.[105,166,300]

About 5% of reported cases of meningococcal disease across age groups in the US are due to outbreaks.[166,300] Outbreaks can occur in communities and institutions such as child care centers, schools, colleges, and military recruit camps; multiple outbreaks of serogroup B have occurred on college campuses.[105,166,300] The incidence of meningococcal disease in the US is highest among infants <1 year of age, followed by children 1–4 years of age.[105,166,300] A second peak of disease incidence is found in young adults 16–23 years of age; incidence also increases again in older adults >85 years of age.[105,166,300] Risk factors of invasive meningococcal disease include travel tc or residence in a country where disease is hyperendemic or epidemic, exposure during an outbreak, household crowding, smoking, antecedent viral upper respiratory infection, persistent complement deficiencies (including use of complement component inhibitors such as eculizumab or ravulizumab), functional or anatomic asplenia, and HIV infection.[166,237,300] Microbiologists who routinely work with isolates of *meningitidis*, college students, men who have sex with men, and military recruits are also at increased risk of disease.[166,237,300]

Clinical Experience with MenB-4C (Bexsero®)

The effectiveness of MenB-4C (Bexsero®) was assessed by measuring serum bactericidal activity (SBA) in 2 types of assay: an assay that used endogenous complement preserved in serum samples from study participants (enc-hSBA), and an assay that used an exogenous source of human complement (hSBA).[1] The enc-hSBA assay assessed for the breadth of immune response against diverse *N. meningitidis* serogroup B strains, including 110 US strains collected between 2000 and 2008, using the sera of study participants.[1] The assay panel included most antigen types found among serogroup B isolates circulating in the US between 2000 and 2017, including some with genetic profiles considered hypervirulent.[1] The serum of each participant was tested against a maximum of 35 strains randomly selected from the panel at a 4-fold dilution.[1] The hSBA assay measured bactericidal activity against 4 serogroup B indicator strains that each corresponded to one of the 4 antigenic components of MenB-4C.[1]

Adolescents and Adults 10 through 25 Years of Age.

A randomized, phase 3, controlled trial assessed the breadth of immune response elicited by MenB-4C, based on the enc-hSBA assay, in adolescents and adults 10–25 years of age in Australia, Canada, Czechia, Estonia, Finland, Turkey, and the US.[1,309] Study participants were randomized to receive either 2 doses of MenB-4C on a 0-, 6-month schedule, 3 doses of MenB-4C on a 0-, 2-, 6-month schedule, an investigational MenABCWY vaccine, or the MenACWY vaccine as a control.[309] The breadth of immune response was assessed using both responder- and test-based analyses.[1,309] The responder-based analyses assessed the percentages ofvaccine recipients whose sera killed ≥70% of the tested strains; the test-based analyses assessed the reduction in relative risk of enc-hSBA tests without bactericidal activity against serogroup B strains following MenB-4C as compared to MenACWY.[1,309] For the responder-based analyses, the breadth of immune response was 89.8% for individuals who received 2 doses of MenB-4C on a 0-, 6-month schedule, and 93.4% for individuals who received 3 doses of MenB-4C on a 0-, 2-, 6-month schedule.[309] For the test-based analyses, the breadth of immune response was 81.8% and 83.2% for the 2-dose schedule and 3-dose schedule of MenB-4C, respectively.[309]

In additional randomized clinical studies, immune responses were assessed using hSBA assays; these were performed using 3 strains of *N. meningitidis* serogroup B, each selected to measure response to 1 of 3 vaccine antigens (i.e., NadA, FHbp, OMV containing PorA [serosubtype P1.4]).[1,12,13]

In a randomized controlled study that included 299 adolescents 11–17 years of age in Canada and Australia who received 2 doses of MenB-4C given 1 month apart (evaluable immunogenicity population), 98, 99, and 39% of vaccine recipients had a 4-fold hSBA response to FHbp, NadA, and OMV, respectively, at 1 month after the second dose; 63% of these individuals had a composite response at 1 month after the second dose.[1,4] In a randomized, controlled extension study involving adolescents 11–17 years of age in Chile who received 2 doses of MenB-4C given 1, 2, or 6 months apart, 90–94% had an antibody response to all 3 *N. meningitidis* serogroup B strains tested (composite response) at 1 month after the second dose and 77–94% had an hSBA titer of 1:4 or greater against all 3 strains tested at 18–24 months after the second dose.[3,13]

In a randomized, controlled study evaluating MenB-4C in 148 adult university students, 18–24 years of age, in the United Kingdom who received 2 doses of MenB-4C given 1 month apart (evaluable immunogenicity population), 78, 94, and 67% of vaccine recipients had a 4-fold hSBA response to FHbp, NadA, and OMV, respectively, at 1 month after the second dose; 24% already had a composite response prior to vaccination (baseline antibody response), 88% had a composite response 1 month after the second dose, and 66% had a composite response 11 months after the second dose.[1]

Adults 26 Years of Age or Older.

MenB-4C has been used for prevention of meningococcal serogroup B infection in healthy **adults 26 years of age or older [off-label]**†.[4,16,19,200] In an open-label study in laboratory personnel routinely exposed to *N. meningitidis* isolates, adults 18 through 25 years of age and **adults 26 through 50 years of age [off-label]**† received a 2-dose regimen of MenB-4C and 83% had an antibody response to at least 1 of the 3 serogroup B antigens tested at 1 month after the second dose.[4]

In other studies that included laboratory personnel **26–65 years of age [off-label]**† at risk of occupational exposure to meningococci, 2 or 3 doses of MenB-4C were administered in conjunction with meningococcal (groups A, C, Y and W-135) oligosaccharide diphtheria CRM_{197} conjugate vaccine (MenACWY-CRM).[16,19]

Clinical Experience with MenB-FHbp (Trumenba®)

Efficacy of MenB-FHbp (Trumenba®) was based on immunogenicity data from 4 clinical studies.[2,4] In these studies, hSBA assays were performed using 4 meningococcal serogroup B strains that express 4 different FHbp variants (A22, A56, B24, B44); the proportion of vaccinees with a 4-fold or greater increase in hSBA titer for each of these 4 strains of *N. meningitidis* serogroup B and the proportion of vaccinees with a titer greater than or equal to the lower limit of quantitation (LLOQ) of the assay for all 4 strains (composite response) was assessed.[2,3,4] To evaluate the efficacy of the 2- and 3-dose schedules of MenB-FHbp against diverse meningococcal serogroup B strains, the proportion of vaccinees achieving a defined hSBA titer of ≥LLOQ following completion of the series was assessed against a panel of 10 additional strains; each of the strains had expression of a different FHbp variant.[2]

Adolescents and Adults 10 through 25 Years of Age.

In a controlled clinical study in adolescents and adults 10–25 years of age in the US and Europe, the immunogenicity of a 2-dose regimen of MenB-FHbp (second dose given 6 months after first dose) was assessed.[2,311] Approximately 1 month after the second dose, the proportions of participants who had a 4-fold or greater increase in hSBA titer for A22, A56, B24, and B44 were 78.3%, 95%, 67.4%, and 86.4%, respectively; the composite hSBA response was 74.3%.[2,311] For the 10 additional test strains, responses ≥LLOQ were comparable to those observed for the primary strains with ranges of 71.1–96.8% following the second dose.[2,311]

In 2 randomized controlled studies, the immunogenicity of a 3-dose regimen of MenB-FHbp (second dose given 2 months after the first dose and third dose given 6 months after the first dose) was assessed in participants in the US, Canada, and Europe.[2,312] One of these studies included adolescents 10-18 years of age, and the other study included adults 18-25 years of age.[2,312] The percentages of participants in the US with an hSBA titer with at least a 4-fold increase for the 4 primary strains (A22, A56, B24, B44) 1 month after the third dose ranged from 81.9–90.2% in adolescents 10–18 years of age and 79.3–90.7% in adults 18–25 years of age.[2] The composite hSBA response was 85.7% and 82.4% for adolescents and adults in the study, respectively.[2] For the 10 additional strains, the percentages of participants in the US with an hSBA titer ≥LLOQ ranged from 76.1–98.9% in adolescent participants and 66.7–98.8% in adult participants.[2]

In another randomized study in adolescents 11–18 years of age in Europe, a 2-dose regimen of MenB-FHbp (second dose given 6 months after the first dose) or a 3-dose regimen of MenB-FHbp (second dose given either 2 or 3 months after the first dose and third dose given 6 months after the first dose) was used.[2,313] In those who received the 2-dose regimen, 73% of vaccinees had a composite response (i.e., at least a 4-fold increase in hSBA titer of the four primary strains [A22, A56, B24, B44]) 1 month after the second dose.[2] In those who received the 3-dose regimen, 52% had a composite response after the second dose and 80–82% had a composite response at 1 month after the third dose.[2]

In a randomized controlled study in adolescents 11–17 years of age, a 3-dose series of MenB-FHbp was used (second and third dose given 2 and 6 months, respectively, after the first dose) and study participants were randomized to also receive a dose of saline or a dose of human papillomavirus quadrivalent (types 6, 11, 16, 18) vaccine recombinant (v4HPV; Gardasil®) concomitantly at a separate site.[2,3,4] Approximately 53% of vaccinees who received MenB-FHbp administered concomitantly with saline had an antibody response to all 4 serogroup B antigens tested (composite antibody response) by 1 month after the second dose, and 84% had a composite response by 1 month after the third dose.[2,3,4] In the group that received each dose of MenB-FHbp concomitantly with a dose of 4vHPV, 50% of vaccinees had a composite antibody response to the meningococcal serogroup B vaccine by 1 month after the second dose, and 81% had a composite antibody response to the vaccine by 1 month after the third dose.[2,3,4]

Adults 26 Years of Age or Older.

MenB-FHbp has been used for the prevention of meningococcal serogroup B infection in healthy **adults 26 years of age or older [off-label]**†.[17,200] In a study that included 7 laboratory personnel **24–62 years of age [off-label]**† who received 3 doses of MenB-FHbp (second dose 2 months after the first dose and third dose 6 months after the first dose), the 6 evaluable vaccinees had hSBA titers equal to or greater than the LLOQ against 3 of the 4 *N. meningitidis* serogroup B strains tested and 3 of these individuals achieved titers equal to or greater than the LLOQ for all 4 strains.[17]

Clinical Perspective

The American Academy of Pediatrics (AAP) and other organizations provide recommendations for the prevention of meningococcal disease caused by *N. meningitidis* serogroup B.[199,200,301,302,310] Immunization against meningococcal serogroup B infection is recommended for certain high-risk groups or populations in adults, adolescents, and children 10–25 years of age.[199,200,301,302,310] High-risk groups and populations include patients with anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, and microbiologists who are routinely exposed to *N. meningitidis*.[199,200,310] A 3-dose primary series at 0, 1–2, and 6 months of either MenB-4C (Bexsero®) or MenB-FHbp (Trumenba®) is recommended for these patients; the same vaccine type should be used for all doses.[199,200,310] The Centers for Disease Control and Prevention (CDC) recommend the meningococcal group B vaccine for children at high risk of serious illness or after shared clinical decision-making with a healthcare provider.[199]

The CDC Advisory Committee on Immunization Practices (ACIP) and AAP recommend meningococcal serogroup B vaccination in adolescents and young adults 16–23 years of age (16–18 years of age preferred), who are not at increased risk for disease, based on shared clinical decision making.[199,200,310] A 2-dose series of either MenB-4C or MenB-FHbp at least 6 months apart is recommended; to optimize rapid protection (e.g., for students starting college in <6 months), a 3-dose series at 0, 1–2, and 6 months may be administered.[199,200,310] The same vaccine type should be used for all doses.[199,200,310]

Although safety and efficacy of MenB vaccine have not been established in adults 26 years of age or older,[1,2] ACIP recommends immunization against meningococcal serogroup B infection in **adults 26 years of age or older [off-label]**† who are at increased risk because of certain chronic medical conditions (e.g., persistent complement component deficiencies; anatomic or functional asplenia, including sickle cell disease; individuals taking eculizumab or ravulizumab) or because of routine exposure to *N. meningitidis* as a microbiologist.[200,300,301,302] A 3-dose series (at 0, 1–2, and 6 months) of either MenB-4C or MenB-FHbp is recommended for these adults; the same vaccine type should be used for all doses.[200,300,301,302]

During pregnancy, ACIP states that immunization against *N. meningitidis* serogroup B should be delayed until after pregnancy due to lack of safety data; AAP states that precaution should be used.[200,300,310] However, immunization may be indicated in pregnancy if the benefits outweigh the potential risks.[200,300,310]

ACIP recommends meningococcal serogroup B vaccination in response to outbreaks among persons 10 years of age and older who are at increased risk of disease.[300,315] Persons at increased risk during an outbreak include those in community or organizational settings and men who have sex with men.[200,300,315] If previously unvaccinated, a 3-dose series at 0, 1–2, and 6 months of either MenB-4C or MenB-FHbp is recommended.[300,301,302] If previously vaccinated, a single booster dose is recommended if 1 year or more has passed after the primary vaccination series; public health professionals might also consider a ≥6-month interval.[300,315] Ideally, the same type of vaccine administered for the primary vaccination series should be used for the booster dose.[315]

Dosage and Administration

▪ General

Dispensing and Administration Precautions

Appropriate medical treatment used to manage immediate allergic reactions must be available in the event an acute anaphylactic reaction occurs following administration of MenB-4C (Bexsero®) or MenB-FHbp (Trumenba®).[1,2]

Syncope (vasovagal or vasodepressor reaction; fainting) may occur following vaccination.[1,2,300] Procedures should be in place to avoid injury following syncope.[1,2,300]

▪ Administration

Two meningococcal group B (MenB) vaccine are commercially available: MenB-4C (Bexsero®) and MenB-FHbp (Trumenba®).[1,2]

MenB-4C and MenB-FHbp are administered *only* by IM injection.[1,2]

The MenB vaccine may be given simultaneously with other age-appropriate vaccines.[306] When multiple vaccines are administered during a single health-care visit, each parenteral vaccine should be given with a different syringe and at different injection sites.[306] Injection sites should be separated by at least 1 inch if possible.[307]

To ensure delivery of vaccine into muscle, IM injections should be made at a 90° angle to the skin using a needle length appropriate for the individual's age and body mass, thickness of adipose tissue and muscle at the injection site, and injection technique.[308]

Improper storage or handling of vaccines may reduce vaccine potency resulting in reduced or inadequate immune response in vaccinees.[305] All vaccines should be inspected upon delivery and monitored during storage to ensure that the appropriate temperature is maintained.[305] In general, vaccines that have been mishandled or not stored at the recommended temperature should not be administered.[305] If there are concerns about mishandling, the manufacturer or state or local immunization or health departments should be contacted for guidance on whether the vaccine is usable.[305]

MenB-4C (Bexsero®)

Immediately prior to administration, the single-dose prefilled syringe containing MenB-4C should be shaken well to obtain a homogeneous suspension.[1] The vaccine should appear as a white, opalescent suspension and should be discarded if it contains particulates, appears discolored, or cannot be resuspended.[1]

MenB-4C should be stored at 2–8°C and protected from light.[1] The vaccine should be protected from freezing and should be discarded if it has been frozen.[1]

MenB-FHbp (Trumenba®)

Immediately prior to administration, the single-dose prefilled syringe containing MenB-FHbp should be shaken well to obtain a homogeneous white suspension.[2] The vaccine should be discarded if it contains particulates, appears discolored, or cannot be resuspended with thorough agitation.[2]

The preferred site of injection of the MenB-FHbp vaccine is the deltoid region of the upper arm.[2]

MenB-FHbp should not be mixed with any other vaccine.[2]

MenB-FHbp should be stored horizontally (flat on a shelf) at 2–8°C; horizontal storage is recommended to minimize redispersion time.[2] The vaccine should be protected from freezing and should be discarded if it has been frozen.[2]

▪ Dosage

MenB-4C (Bexsero®) and MenB-FHbp (Trumenba®) are given in a series of either 2 or 3 doses.[1,2] Each dose consists of the entire contents (0.5 mL) of the commercially available single-dose prefilled syringe containing the vaccine.[1,2]

The choice of dosing schedule (i.e., number and timing of doses) may depend on the individual's risk of exposure and susceptibility to *Neisseria meningitidis* serogroup B.[1,2]

The manufacturers state that data available to date are insufficient regarding the interchangeability of MenB-4C and MenB-FHbp to complete the vaccination series.[1,2] The US Public Health Service Advisory Committee on Immunization Practices (ACIP) and American Academy of Pediatrics (AAP) state that MenB-4C and MenB-FHbp are not interchangeable and recommend that the meningococcal group B (MenB) vaccine used for the initial dose should be used to complete the vaccination series, as well as for any booster doses.[20,300,301,302]

Consult the US Centers for Disease Control and Prevention (CDC)/ACIP vaccination schedules for additional information, including specific detailed recommendations for specific scenarios and conditions.[199,200]

Prevention of Meningococcal Group B Infection

Adults at Increased Risk for Serogroup B Meningococcal Disease.

For routine immunization in adults at increased risk for meningococcal serogroup B disease (i.e., individuals with certain chronic medical conditions, such as anatomic or functional asplenia, complement component deficiencies, or complement inhibitor use; microbiologists with routine exposure to *N. meningitidis* isolates; or individuals at increased risk during an outbreak such as in community or organizational settings, and among men who have sex with men), ACIP recommends administration of either the 3-dose MenB-4C series or 3-dose MenB-FHbp series.[300,301,302]

The 3-dose schedule of MenB-4C or MenB-FHbp is as follows: 0.5 mL administered IM at 0, 1–2, and 6 months.[1,2,302] If the interval between the first and second dose is ≥6 months, then the third dose is not needed.[302] If the third dose is administered <4 months after the second dose, then the dose should be repeated ≥4 months after the last dose, unless the third dose was administered ≥6 months after the first dose.[302]

If the individual remains at increased risk for meningococcal disease, administer a **booster dose [off-label]**† at 1 year after the completion of the primary series, then every 2–3 years thereafter.[300] During an outbreak, a one-time **booster dose [off-label]**† is also recommended if it has been ≥1 year since completion of the primary series (a ≥6 month interval may also be considered by public health professionals).[300]

Although MenB-4C and MenB-FHbp are FDA-approved in adults 19–25 years of age, the primary series MenB vaccination may be administered in **adults ≥26 years of age [off-label]**†.[300]

Adolescents and Adults 16–23 Years of Age Not at Increased Risk for Meningococcal Disease.

For vaccination of healthy adolescents and young adults 16–23 years of age, ACIP and AAP recommend either the 2-dose MenB-4C series or 2-dose MenB-FHbp series on the basis of shared clinical decision-making.[300,301,302,310] ACIP and AAP state that the preferred age for meningococcal B vaccination is 16–18 years of age.[20,300,301,302,310]

The 2-dose schedule of MenB-4C or MenB-FHbp is as follows: 0.5 mL administered IM at 0 and 6 months.[1,2,302,310] If the second dose is administered earlier than 6 months after the first dose, administer a third dose ≥4 months after the second dose.[1,2,302,310]

Booster doses are not recommended unless the person becomes at increased risk for meningococcal disease.[300]

Children and Adolescents ≥10 Years of Age at Increased Risk for Serogroup B Meningococcal Disease.

Although FDA-approved in children and adolescents ≥10 years of age, use of MenB-4C or MenB-FHbp in individuals 10–15 years of age who are *not* at risk for infection is not recommended.[1,2,300]

For primary immunization in children ≥10 years of age at increased risk for meningococcal serogroup B disease (i.e., children with certain chronic medical conditions, such as anatomic or functional asplenia, complement component deficiencies, or complement inhibitor use; or children at increased risk during an outbreak such as in community or organizational settings), ACIP and AAP recommend administration of either the 3-dose MenB-4C series or 3-dose MenB-FHbp series.[300,301,302,310]

The 3-dose schedule of MenB-4C or MenB-FHbp is as follows: 0.5 mL administered IM at 0, 1–2, and 6 months.[1,2,302,310] If the interval between the first and second dose is ≥6 months, then the third dose is not needed.[302,310] If the third dose is administered <4 months after the second dose, then the dose should be repeated ≥4 months after the last dose, unless the third dose was administered ≥6 months after the first dose.[302,310]

If the individual remains at increased risk, administer a **booster dose [off-label]**† at 1 year after the completion of the primary series, then every 2–3 years thereafter.[300] During an outbreak, a one-time **booster dose [off-label]**† is also recommended if it has been ≥1 year since completion of the primary series (a ≥6 month interval may also be considered by public health professionals).[300]

▪ Special Populations

Hepatic Impairment

The manufacturers make no specific dosage recommendations for individuals with hepatic impairment.[1,2]

Renal Impairment

The manufacturers make no specific dosage recommendations for individuals with renal impairment.[1,2]

Geriatric Patients

The manufacturers make no specific dosage recommendations for geriatric individuals.[1,2]

Cautions

▪ Contraindications

MenB-4C (Bexsero®): Hypersensitivity, including severe allergic reactions, to any component of the vaccine or a previous dose of the vaccine.[1]

MenB-FHbp (Trumenba®): Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.[2]

▪ Warnings/Precautions

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., anaphylaxis, rash, eye swelling) have been reported after administration of MenB-4C.[1]

Appropriate medical treatment (e.g., epinephrine) should be readily available in case an anaphylactic reaction occurs following administration of MenB-4C or MenB-FHbp.[1,2]

Syncope

Syncope (fainting) can occur following administration of vaccines, including MenB-4C and MenB-FHbp.[1,2,300]

Providers should consider monitoring individuals (especially adolescents) for 15 minutes after vaccination, with the individual seated or lying down, to reduce the risk of injury in case of fainting.[300] If syncope occurs, the vaccine recipient should be observed until symptoms resolve.[300]

Individuals with Altered Immunocompetence

Some individuals with altered immunocompetence may have a reduced immune response to MenB-4C or MenB-FHbp.[1,2]

Persons with certain complement deficiencies and persons treated with terminal complement activation inhibitors (e.g., eculizumab) are at increased risk for invasive disease caused by *N. meningitidis* serogroup B even if they develop antibodies after receiving the meningococcal group B (MenB) vaccine.[1,2]

Limitations of Vaccine Effectiveness

MenB vaccine (MenB-4C, MenB-FHbp) may not protect all vaccine recipients against meningococcal serogroup B infection.[1,2] The manufacturer of MenB-4C states that the vaccine may not provide protection against all meningococcal serogroup B strains.[1]

Specific Populations

Pregnancy.

The manufacturers state that there are no adequate and well-controlled studies using the MenB vaccine (MenB-4C, MenB-FHbp) in pregnant women; available human data on MenB-4C or MenB-FHbp administered to pregnant women are insufficient to inform vaccine-associated risks during pregnancy.[1,2]

In a developmental toxicity study in female rabbits administered MenB-4C (0.5 mL dose at each occasion) prior to mating and during gestation, no adverse effects on fetal or pre-weaning development were observed due to the vaccine.[1] Similarly, in two developmental toxicity studies in female rabbits administered MenB-FHbp (0.5 mL dose at each occasion) prior to mating and during gestation, no adverse effects on fetal or pre-weaning development were observed.[2]

ACIP states that administration of MenB vaccine should be deferred in pregnant individuals, unless the individual is at increased risk for meningococcal serogroup B disease and benefits of vaccination outweigh potential risks.[300]

Lactation.

It is not known whether the vaccine components of MenB-4C are distributed into human milk.[1] Available data are insufficient to assess the effects of MenB-4C or MenB-FHbp on breast-fed infants or on milk production/excretion.[1,2]

Consider the developmental and health benefits of breast-feeding along with the mother's clinical need for the MenB vaccine and any potential adverse effects on the breast-fed child from the vaccine or from susceptibility to meningococcal disease.[1,2]

Pediatric Use.

MenB-4C (Bexsero®): Safety and efficacy have not been established in pediatric children younger than 10 years of age.[1]

MenB-FHbp (Trumenba®): Safety and efficacy have not been established in children younger than 10 years of age.[2] In a clinical study in **infants younger than 12 months of age [off-label]**† who received a reduced dosage of MenB-FHbp, fever occurred in 90% of vaccinees.[2] Clinical data strongly suggest that a 2-dose series of MenB-FHbp would not be effective in children 1 to <10 years of age.[2]

Geriatric Use.

MenB-4C and MenB-FHbp: Safety and efficacy have not been established in adults >65 years of age.[1,2]

▪ Common Adverse Effects

MenB-4C: The most common adverse reactions (≥10%) are pain at the injection site, fatigue, headache, nausea, erythema, myalgia, and swelling.[1]

MenB-FHbp: The most common adverse reactions in adolescents and young adults are pain at the injection site, fatigue, headache, and muscle pain.[2]

Drug Interactions

▪ Immune Globulins

Generally, immune globulin products from the US interact minimally with inactivated vaccines.[303]

The Centers for Disease Control and Prevention (CDC) states that inactivated vaccines such as meningococcal vaccines may be given simultaneously with (using different injection sites) or at any time interval before or after immune globulin preparations.[303]

▪ Immunosuppressive Agents

Immune responses to meningococcal group B (MenB) vaccine may be reduced in some individuals with altered immunocompetence.[1,2] Persons treated with terminal complement activation inhibitors (e.g., eculizumab) are at increased risk for invasive disease caused by *N. meningitidis* serogroup B even if they develop antibodies after receiving the MenB vaccine.[1,2]

The US Public Health Service Advisory Committee on Immunization Practices (ACIP) states that inactivated vaccines generally can be administered safely to individuals with altered immunocompetence.[304] However, if possible, vaccination should be avoided during chemotherapy or radiation therapy.[304] Individuals vaccinated within 14 days before starting immunosuppressive therapy or while receiving immunosuppressive therapy should be considered unimmunized and should be revaccinated at least 3 months after such therapy is discontinued if immunocompetence has been restored.[304]

▪ Vaccines

The ACIP states that the MenB vaccine may be administered simultaneously with other age-appropriate vaccines.[306] However, each parenteral vaccine should be administered using a different syringe and at a different injection site.[306]

Inactivated Vaccines and Toxoids

Diphtheria and Tetanus Toxoids and Pertussis Vaccines.

MenB-FHbp (Trumenba®) has been administered concurrently with tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed (Tdap; Adacel®) in adolescents 10–12 years of age.[2] The noninferiority criteria were met for all immunogenicity endpoints for the MenB strains and Tdap antigens.[2]

MenB-FHbp (Trumenba®) also has been administered concurrently with a fixed-combination vaccine containing diphtheria, tetanus, pertussis, and poliovirus antigens (Tdap/IPV) in healthy adolescents 11 to younger than 19 years of age without a decrease in antibody responses to Tdap/IPV.[3,4,18]

Human Papillomavirus Vaccine.

MenB-FHbp (Trumenba®) has been administered concurrently with human papillomavirus quadrivalent (types 6, 11, 16, 18) vaccine recombinant (4vHPV; Gardasil®) in adolescents 11–17 years of age.[2] The immune responses for most HPV types (i.e., HPV types 6, 11, 16) and meningococcal serogroup B strains met the required noninferiority criteria.[2] For HPV type 18, the immune response was slightly lower than the required noninferiority criteria.[2] However, at least 99% of vaccinees achieved seroconversion for all 4 HPV antigens.[3,4]

Meningococcal Vaccine.

MenB-FHbp (Trumenba®) has been administered concurrently with meningococcal (groups A, C, Y, and W-135) polysaccharide diphtheria toxoid conjugate vaccine (MenACWY-D; Menactra® [no longer available in the US]) in adolescents 10–12 years of age.[2] The noninferiority criteria were met for all immunogenicity endpoints for the MenB strains and MenACWY antigens.[2]

MenB-4C (Bexsero®) has been administered concurrently or sequentially with meningococcal (groups A, C, Y and W-135) oligosaccharide diphtheria CRM197 conjugate vaccine (MenACWY-CRM; Menveo®) in laboratory personnel 18–65 years of age at risk for meningococcal disease because of exposure to *Neisseria meningitidis* in the laboratory environment.[16,19] In one study in healthy adults 18–50 years of age routinely exposed to *N. meningitidis* in a laboratory setting, 3 doses of MenB-4C (second dose 2 months after the first dose and third dose 6 months after the first dose) were administered followed by a single dose of MenACWY-CRM (Menveo®) given 1 month later.[16] Among study participants with baseline serum bactericidal activity with human complement (hSBA) titers less than 4 against 1 or more *N. meningitidis* serogroup B strains, at least 89% had hSBA titers of 4 or greater after the second dose and at least 90% had hSBA titers of 4 or greater after the third dose of MenB-

4C.[16] At 1 month after the single dose of MenACWY-CRM, the majority of study participants had hSBA titers of 8 or greater against *N. meningitidis* serogroups A, C, Y, and W-135.[16] In another study in laboratory personnel 18–65 years of age, the first dose of MenB-4C was administered concurrently with MenACWY-CRM, followed by a second and third dose of MenB-4C given 3 and 6 months later, without any unusual adverse effects.[19]

ACIP states that the MenB vaccine (MenB-4C or MenB-FHbp) may be administered simultaneously with the MenACWY vaccine (Menveo® or MenQuadfi®).[306] However, each vaccine should be administered at a different injection site, if feasible.[306]

Description

Meningococcal group B (MenB) vaccine is commercially available in the US as 2 different inactivated (recombinant) vaccines (MenB-4C and MenB-FHbp) containing antigens derived from immunogenic proteins found on the cell surface of *Neisseria meningitidis* (*N. meningitidis*) serogroup B.[1,2,3,11,14,15] The antigens contained in MenB vaccine promote production of specific antibodies that activate complement-mediated killing of meningococci to provide protection against infection by strains of *N. meningitidis* serogroup B represented in the vaccine.[1,2,3,11,14,15]

MenB-4C (Bexsero®) is a white, opalescent suspension that contains 3 recombinant *N. meningitidis* serogroup B surface proteins (neisserial adhesin A [NadA], neisserial heparin-binding antigen [NHBA], factor H-binding protein [FHbp]); it also contains outer membrane vesicles (OMV) containing outer membrane protein PorA (serosubtype P1.4).[1,3,15] The 3 surface protein components (NadA, NHBA, FHbp) are produced using recombinant DNA technology in *Escherichia coli* and purified by column chromatography.[1] The OMV protein component (PorA P1.4) is produced by fermentation of a strain of *N. meningitidis* that expresses PorA P1.4 and inactivated using deoxycholate.[1] The antigens are then adsorbed onto aluminum hydroxide.[1] In addition to these antigens, each 0.5-mL dose of MenB-4C contains aluminum hydroxide (1.5 mg), sodium chloride (3.125 mg), histidine (0.776 mg), sucrose (10 mg), and kanamycin (no more than 0.01 mcg).[1]

MenB-FHbp (Trumenba®) is a suspension that contains 2 recombinant lipidated FHbp antigens, one from FHbp subfamily A (A05) and one from FHbp subfamily B (B01).[2,3,11] The 2 outer membrane protein components (FHbp A05 and FHbp B01) are produced using recombinant DNA technology in *E. coli* and purified by column chromatography.[2,14] In addition to these antigens, each 0.5-mL dose of MenB-FHbp contains 0.25 mg of aluminum (provided as aluminum phosphate) and 18 mcg of polysorbate 80 in 10mM histidine-buffered saline.[2]

Following IM administration of MenB vaccine (MenB-4C or MenB-FHbp), complement-mediated antibody response to the antigens contained in the vaccine is measured as serum bactericidal activity with human complement (hSBA).[1,2,3,4,11,14] An hSBA titer of at least 4 (serum dilution of 1:4) in response to the MenB vaccine antigens is generally accepted as correlating with protection against *N. meningitidis* serogroup B.[11,15] However, susceptibility of *N. meningitidis* serogroup B to complement-mediated antibody-dependent killing following vaccination with MenB-4C or MenB-FHbp depends on the degree of similarity between the vaccine antigens and the invading strain of *N. meningitidis* serogroup B and the amount of antigen expressed on the surface of the invading strain.[1,2,14]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus) (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Prior to administration of each vaccine dose, provide a copy of the appropriate Centers for Disease Control and Prevention (CDC) Vaccine Information Statement (VIS) to the patient or patient's parent or guardian (VISs are available at https://www.cdc.gov/vaccines/hcp/vis/index.html (https://www.cdc.gov/vaccines/hcp/vis/index.html)).[1,2,5]
- Advise the patient and/or the patient's parent or guardian of the risks and benefits of vaccination with meningococcal group B (MenB) vaccine.[1,2]
- Advise the patient and/or the patient's parent or guardian of the importance of completing the vaccination series using the recommended number of doses of MenB-4C or MenB-FHbp, unless contraindicated.[1,2]
- Advise patient and/or patient's parent or guardian that MenB vaccine may not provide protection in all vaccinees.[1,2]
- Advise the patient and/or the patient's parent or guardian that fainting (sometimes resulting in falling with injury) has been reported following vaccination, and that patients should sit or lie down during and for 15 minutes after vaccine administration.[1,2,300]
- Advise the patient and/or the patient's parent or guardian to inform clinicians of a history of allergic reactions to MenB vaccine or any vaccine component.[1,2]
- Advise the patient and/or the patient's parent or guardian of the importance of contacting the clinician if any adverse reactions (including allergic reactions) occur with MenB vaccine.[1,2] Clinicians or individuals can report any adverse reactions that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or https://vaers.hhs.gov/index (https://vaers.hhs.gov/index) .[1,2]
- Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs, and any concomitant illnesses.[1,2]
- Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.[1,2]
- Advise patients of other important precautionary information.[1,2]

Additional Information

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Meningococcal Group B Vaccine (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Meningococcal+Group+B+Vaccine&collapse=1)

Parenteral

Injectable suspension, for IM use

50 mcg of meningococcal B NadA protein, 50 mcg of meningococcal B NHBA fusion protein, 50 mcg of meningococcal B FHbp fusion protein, and 25 mcg of meningococcal B outer membrane vesicle per 0.5 mL

Bexsero®, GlaxoSmithKline (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=GlaxoSmithKline&collapse=1)

60 mcg of meningococcal B FHbp A05 protein and 60 mcg of meningococcal B FHbp B01 protein per 0.5 mL

Trumenba®, Pfizer (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=Pfizer&collapse=1)

Related Resources

AHFS Patient Medication Information (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Meningococcal%20Group%20B%20Vaccine) and other related patient health topics (MedlinePlus)
ASHP Drug Shortages Resource Center (https://www.ashp.org/Drug-Shortages)
CCRIS (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+ccris:%%22Meningococcal%20Group%20B%20Vaccine%%22) (Chemical Carcinogenesis Research Information System)
ChemID*plus* (https://chem.nlm.nih.gov/chemidplus/name/Meningococcal%20Group%20B%20Vaccine)
Biochemical Data Summary (http://www.drugbank.ca/unearth/q?utf8=%%E2%%9C%%93&query=Meningococcal%20Group%20B%20Vaccine&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withd (US and Canada)
Clinical Trials (https://www.clinicaltrials.gov/ct/search?submit=Search&term=Meningococcal%20Group%20B%20Vaccine)
DailyMed (https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=Meningococcal%20Group%20B%20Vaccine) (drug labels)
DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%%22Meningococcal%20Group%20B%20Vaccine%%22) (Developmental and Reproductive Toxicology Database)
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=Meningococcal%20Group%20B%20Vaccine) (approval information)
European Medicines Agency (https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=Meningococcal%20Group%20B%20Vaccine)
FDA National Drug Code Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Meningococcal%20Group%20B%20Vaccine&collapse=1)
FDA Recalls, Market Withdrawals, and Safety Alerts (https://www.fda.gov/Safety/Recalls/default.htm)
HSDB (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:%%22Meningococcal%20Group%20B%20Vaccine%%22) (Hazardous Substances Data Bank)
Inxight Drugs (https://drugs.ncats.io/substances?q=%%22Meningococcal%20Group%20B%20Vaccine%%22) (National Center for Advancing Translational Sciences)
LactMed (drug effects on breastfeeding) (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%%28@na+%%22Meningococcal%20Group%20B%20Vaccine%%22+%%29)
New Drug Approvals (https://ahfs.ashp.org/drug-assignments.aspx)
Orange Book (https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?panel=0&drugname=Meningococcal%20Group%20B%20Vaccine) (therapeutic equivalence)
PharmGKB (https://www.pharmgkb.org/search?connections&gaSearch=Meningococcal%20Group%20B%20Vaccine&query=Meningococcal%20Group%20B%20Vaccine&type=chemical) (Pharmacogenomic data from PharmGKB)
Pillbox (*beta*) (https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=Meningococcal%20Group%20B%20Vaccine) (drug identification and images)
PubMed (https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=Meningococcal%20Group%20B%20Vaccine%%5BAll+Fields%%5D) (scientific journals)
Safety-related Labeling Changes (https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges) (FDA/CDER)
ToxLine (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+toxline:%%22Meningococcal%20Group%20B%20Vaccine%%22) (Toxicology Literature Online)

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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