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# Vaccine Safety

Vaccine Safety Home

# Meningococcal Vaccines

**Safety Information** 

# **About Meningococcal Disease**

Meningococcal disease can refer to any illness that is caused by a type of bacteria called *Neisseria meningitidis*, also known as meningococcus. These illnesses are often severe and can be deadly. They include infections of the lining of the brain and spinal cord (meningitis) and bloodstream infections (bacteremia or septicemia).

There are 6 serogroups (a group of bacteria that are closely related) of *N. meningitidis* that cause most meningococcal disease in the world. They are referred to as serogroups A, B, C, W, X, and Y. These bacteria spread through the exchange of respiratory and throat secretions (like spit). This can occur when living in close quarters, sharing food or beverages, or kissing.

*N. meningitidis* is a leading cause of bacterial meningitis in children ages 2 through 18 years in the United States. There are safe and effective vaccines that can protect against meningococcal disease.

Learn more about meningococcal disease.

### **Vaccine Information Statements**

Vaccine Information Statements (VISs) are information sheets produced by CDC that explain both the benefits and risks of a vaccine.

### MenACWY

Meningococcal ACWY vaccine for adolescents and specific populations.

#### MenB

Meningococcal B vaccine for adolescents and adults of specific populations.

### **Available Vaccines**

There are two types of vaccines available in the United States that can safely prevent meningococcal disease. They are (1) quadrivalent meningococcal conjugate or MenACWY vaccines and (2) serogroup B meningococcal or MenB vaccines.

**MenACWY vaccine** protects against meningococcal disease caused by serogroups A, C, W, and Y.

MenB vaccine protects against meningococcal disease caused by serogroup B.

### Who Should Get MenACWY Vaccine

CDC recommends adolescents receive two doses of MenACWY vaccine:

- First dose given to 11- or 12-year-olds
- Second (booster) dose given to 16-year-olds

Other than adolescents, MenACWY vaccine is recommended for anyone 2 months of age or older who:

- Is at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- Has HIV
- Has had their spleen damaged or removed, including people with sickle cell disease
- Has a rare immune condition called persistent complement component deficiency
- Is taking a complement inhibitor drug, such as eculizumab (brand name: Soliris®) or ravulizumab (brand name: Ultomiris®)
- Is a microbiologist who routinely works with isolates of *meningitidis*
- Is living in or traveling to a part of the world where meningococcal disease epidemics occur frequently. Areas with highest incidence include a region of sub-Saharan Africa, shown on this map, that extends laterally all the way from Senegal to Ethiopia
- Is a college freshman living in a residence hall who has not been completely vaccinated with MenACWY vaccine
- Is a U.S. military recruit.

Talk with your healthcare provider about vaccines.

They can answer questions and offer advice based on your specific health needs.

### Who Should Get MenB Vaccine

Teens and young adults (16 through 23 years old) may also get a MenB vaccine. The preferred ages for MenB vaccination are 16 through 18 years old. Multiple doses of the same brand are needed for best protection. Younger children and adults usually do not need MenB vaccines. However, CDC recommends MenB vaccine for anyone 10 years or older who:

- Is at risk because of serogroup meningococcal B disease outbreak
- Had their spleen damaged or removed, including people with sickle cell disease
- Has a rare immune condition called persistent complement component deficiency
- Is taking a complement inhibitor drug, such as eculizumab (brand name: Soliris®) or ravulizumab (brand name: Ultomiris®)
- Is a microbiologist who routinely works with isolates of *meningitidis*

For more information, see Who should get meningococcal vaccination.



Child and Adult Immunization Schedules

Get CDC's official recommended immunization schedules for children, adolescents, and adults.

### Manufacturer Package Inserts

MenACWY Vaccines

Menactra [PDF – 43 Pages] ☑: The Food and Drug Administration (FDA) approved this vaccine in 2005. Menactra® is approved for people aged 9 months through 55 years to protect against invasive meningococcal disease caused by serogroups A, C, W, and Y.

Menveo [PDF – 33 Pages] ☑: FDA approved this vaccine in 2010. Menveo® is approved for people aged 2 months through 55 years of age to protect against invasive meningococcal disease caused by serogroups A, C, W, and Y.

MenQuadfi [PDF – 22 Pages] ☐: FDA approved this vaccine in 2020. MenQuadfi<sup>™</sup> is approved for people ages 2 years and older to protect against invasive meningococcal disease caused by serogroups A, C, W, and Y.

MenB Vaccines



Trumenba [PDF – 18 Pages] ☑: FDA approved this vaccine in 2014. Trumenba® is approved for people ages 10 through 25 years to protect against invasive meningococcal disease caused by serogroup B.

Bexsero [PDF – 13 Pages] : FDA approved this vaccine in 2015. Bexsero is approved for people ages 10 through 25 years to protect against invasive meningococcal disease caused by serogroup B.

### Common Side Effects

MenACWY and MenB vaccines are safe and effective at preventing meningococcal disease. Vaccines, like any medicine, can have side effects. The most common side effects are usually mild and go away on their own.



### Severe allergic reactions following vaccination are rare, but can be life threatening.

Symptoms of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.

If such reactions occur, call 9-1-1 and get the person to the nearest hospital.

### MenACWY Vaccine

#### **Common Side Effects**

- Soreness, redness or swelling where the shot was given
- Muscle pain
- Headache
- Feeling tired (fatigue)

Most side effects are mild to moderate and last from 1 to 3 days.

### Who Should Not Get MenACWY Vaccine

A person should talk with their healthcare provider before getting a MenACWY vaccine if they:

- Had a severe allergic reaction after a previous dose of MenACWY vaccine
- Had a severe allergic reaction after a previous dose of a diphtheria toxoid-, CRM<sub>197</sub>-, or tetanus toxoid-containing vaccine (e.g., Menactra, Menveo, Menquadfi, or any DTaP vaccine)
- Have any severe life-threatening allergies

In some cases, the healthcare provider may decide to postpone MenACWY vaccination to a future visit.

People with minor illnesses (such as a cold) may be vaccinated.

People who are moderately or severely ill should wait until they recover before getting a MenACWY vaccine.

### MenB Vaccine

### **Common Side Effects**

- Soreness, redness or swelling where the shot was given
- Headache
- Feeling tired (fatigue)
- Muscle or joint pain
- Fever

Most side effects are mild to moderate and last from 1 to 3 days.

### Who Should Not Get MenB Vaccine

MenB vaccines should not be given to anyone younger than 10 years of age.

A person should talk with their healthcare provider before getting a MenB vaccine if they:

- Had an allergic reaction after a previous dose of MenB vaccine
- Have any severe, life-threatening allergies
- Are pregnant or breastfeeding
- Have a latex allergy (precaution for Bexsero)

In some cases, the healthcare provider may decide to postpone MenB vaccination to a future visit.

People with minor illnesses (such as a cold) may be vaccinated.

People who are moderately or severely ill should wait until they recover before getting a MenB vaccine.

More information about contraindications and precautions.

### Report Possible Adverse Events To VAERS

The Vaccine Adverse Event Reporting System (VAERS) is an early warning system, co-managed by CDC and FDA, that monitors for potential vaccine safety problems.

Healthcare providers and vaccine manufacturers are required by law to report certain adverse events following vaccination to VAERS; patients and caregivers can also submit reports.

For more information, see Report an Adverse Event to VAERS .

### More Information

### Meningococcal Vaccination: What Everyone Should Know

What everyone should know about meningococcal vaccines.

#### Who Should Not Get Vaccinated?

Some people should not get certain vaccines or should wait before getting them. Read the CDC guidelines for each vaccine.

#### Meningococcal Vaccines – ACIP Recommendations and Guidance

Official guidance on meningococcal vaccines from the Advisory Committee on Immunization Practices (ACIP).

### Meningococcal Vaccination: Information for Healthcare Professionals

Information for healthcare professionals on meningococcal vaccines.

# A Closer Look at the Safety Data

#### Which adverse events are considered "serious?"

By the Code of Federal Regulations (CFR) Title 21 🖸 , an adverse event is defined as serious if it involves any of the following outcomes:

- Death
- A life-threatening adverse event
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Hospitalization, or prolongation of existing hospitalization

Learn more about adverse events.

Findings from vaccine safety monitoring systems and scientific studies have shown that MenACWY and MenB vaccines have a favorable safety profile—the body of scientific evidence overwhelmingly supports their safety.

#### **Menactra Safety Data**

After Menactra (MenACWY vaccine) was licensed for use in 2005, there were reports submitted to VAERS that suggested a potential for an increased risk of Guillain-Barré syndrome (GBS) following Menactra vaccination.

GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. While the cause is not fully understood, the syndrome often follows infection with a virus or bacteria. Learn more about GBS.

The vaccine manufacturers changed the package insert for Menactra to identify a history of GBS as a precaution to vaccination. Subsequently, this precaution was added to other MenACWY vaccines.

Following the VAERS findings, two large safety studies were done to evaluate the risk of GBS after Menactra vaccination. The two studies combined found that the risk for GBS after Menactra vaccination was not increased over the usual (non-vaccine related) GBS rate among people ages 11 to 21 years.

Based on these studies, the Advisory Committee on Immunization Practices (ACIP) **no longer considers a history of GBS to be a contraindication nor precaution for meningococcal vaccination**.

**Source:** No risk of Guillain-Barré Syndrome found after meningococcal conjugate vaccination in two large cohort studies [Pharmacoepidemiol Drug Saf. 2012]

## **How CDC Monitors Vaccine Safety**

CDC and FDA monitor the safety of vaccines after they are approved or authorized. If a problem is found with a vaccine, CDC and FDA will inform health officials, health care providers, and the public.

CDC uses 3 systems to monitor vaccine safety:

- The Vaccine Adverse Event Reporting System (VAERS): an early warning system, co-managed by CDC and FDA, to monitor for potential vaccine safety problems. Anyone can report possible vaccine side effects to VAERS.
- The Vaccine Safety Datalink (VSD): a collaboration between CDC and 13 healthcare organizations that conducts vaccine safety monitoring and research.
- The Clinical Immunization Safety Assessment (CISA) Project: a partnership between CDC and several medical research centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

### **Related Scientific Articles**

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CDC. Update: Guillain-Barré syndrome among recipients of Menactra meningococcal conjugate vaccine – United States, October 2005-February 2006. MMWR Morb Mortal Wkly Rep. 2006 Apr 7;55(13):364-6.

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