VACCINE INFORMATION STATEMENT

Meningococcal B Vaccine:

What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Meningococcal B vaccine can help protect against **meningococcal disease** caused by serogroup B. A different meningococcal vaccine is available that can help protect against serogroups A, C, W, and Y.

Meningococcal disease can cause meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, loss of limbs, nervous system problems, or severe scars from skin grafts.

Meningococcal disease is rare and has declined in the United States since the 1990s. However, it is a severe disease with a significant risk of death or lasting disabilities in people who get it.

Anyone can get meningococcal disease. Certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*, the bacteria that cause meningococcal disease
- People at risk because of an outbreak in their community

2. Meningococcal B vaccine

For best protection, more than 1 dose of a meningococcal B vaccine is needed. There are two meningococcal B vaccines available. The same vaccine must be used for all doses.

Meningococcal B vaccines are recommended for people 10 years or older who are at increased risk for serogroup B meningococcal disease, including:

- People at risk because of a serogroup B meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called "complement component deficiency"
- Anyone taking a type of drug called a "complement inhibitor," such as eculizumab (also called "Soliris"®) or ravulizumab (also called "Ultomiris"®)
- Microbiologists who routinely work with isolates of *N. meningitidis*

These vaccines may also be given to anyone 16 through 23 years old to provide short-term protection against most strains of serogroup B meningococcal disease, based on discussions between the patient and health care provider. The preferred age for vaccination is 16 through 18 years.

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3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of meningococcal B vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant or breastfeeding**

In some cases, your health care provider may decide to postpone meningococcal B vaccination until a future visit.

Meningococcal B vaccination should be postponed for pregnant people unless the person is at increased risk and, after consultation with their health care provider, the benefits of vaccination are considered to outweigh the potential risks.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting meningococcal B vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Soreness, redness, or swelling where the shot is given, tiredness, headache, muscle or joint pain, fever, or nausea can happen after meningococcal B vaccination. Some of these reactions occur in more than half of the people who receive the vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**.

VACCINE INFORMATION STATEMENT

Meningococcal ACWY Vaccine:
What You Need to Know

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1. Why get vaccinated?

Meningococcal ACWY vaccine can help protect against **meningococcal disease** caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available that can help protect against serogroup B.

Meningococcal disease can cause meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, loss of limbs, nervous system problems, or severe scars from skin grafts.

Meningococcal disease is rare and has declined in the United States since the 1990s. However, it is a severe disease with a significant risk of death or lasting disabilities in people who get it.

Anyone can get meningococcal disease. Certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*, the bacteria that cause meningococcal disease
- People at risk because of an outbreak in their community

2. Meningococcal ACWY vaccine

Adolescents need 2 doses of a meningococcal ACWY vaccine:

- First dose: 11 or 12 year of age
- Second (booster) dose: 16 years of age

In addition to routine vaccination for adolescents, meningococcal ACWY vaccine is also recommended for **certain groups of people**:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- People with HIV
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called "complement component deficiency"
- Anyone taking a type of drug called a "complement inhibitor," such as eculizumab (also called "Soliris"®) or ravulizumab (also called "Ultomiris"®)
- Microbiologists who routinely work with isolates of *N. meningitidis*
- Anyone traveling to or living in a part of the world where meningococcal disease is common, such as parts of Africa
- College freshmen living in residence halls who have not been completely vaccinated with meningococcal ACWY vaccine
- U.S. military recruits

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3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of meningococcal ACWY vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone meningococcal ACWY vaccination until a future visit.

There is limited information on the risks of this vaccine for pregnant or breastfeeding people, but no safety concerns have been identified. A pregnant or breastfeeding person should be vaccinated if indicated.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting meningococcal ACWY vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Redness or soreness where the shot is given can happen after meningococcal ACWY vaccination.
- A small percentage of people who receive meningococcal ACWY vaccine experience muscle pain, headache, or tiredness.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

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- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**.

VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

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1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu.**

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

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4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

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- Contact the Centers for Disease Control and Prevention (CDC):
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  - Visit CDC's website at **www.cdc.gov/flu**.

VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Live, Intranasal): *What You Need to Know*

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1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Live, attenuated influenza vaccine

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

Live, attenuated influenza vaccine (called "LAIV") is a nasal spray vaccine that may be given to non-pregnant people 2 **through 49 years of age**.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Is **younger than 2 years or older than 49 years** of age
- Is **pregnant**. Live, attenuated influenza vaccine is not recommended for pregnant people
- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Is a **child or adolescent 2 through 17 years of age who is receiving aspirin or aspirin- or salicylate-containing products**
- Has a **weakened immune system**
- Is a **child 2 through 4 years old who has asthma or a history of wheezing** in the past 12 months
- Is **5 years or older and has asthma**
- Has **taken influenza antiviral medication** in the last 3 weeks
- **Cares for severely immunocompromised people** who require a protected environment
- Has other **underlying medical conditions** that can put people at higher risk of serious flu complications (such as **lung disease, heart disease, kidney disease**

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like diabetes, kidney or liver disorders, neurologic or neuromuscular or metabolic disorders)
- Does **not have a spleen**, or has a **non-functioning spleen**
- Has a **cochlear implant**
- Has a **cerebrospinal fluid leak** (a leak of the fluid that surrounds the brain to the nose, throat, ear, or some other location in the head)
- Has had **Guillain-Barré Syndrome** within 6 weeks after a previous dose of influenza vaccine

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

For some patients, a different type of influenza vaccine (inactivated or recombinant influenza vaccine) might be more appropriate than live, attenuated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Runny nose or nasal congestion, wheezing, and headache can happen after LAIV vaccination.
- Vomiting, muscle aches, fever, sore throat, and cough are other possible side effects.

If these problems occur, they usually begin soon after vaccination and are mild and short-lived.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

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  - Visit CDC's website at **www.cdc.gov/flu**.