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.

Anyone can get meningococcal disease but 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 "persistent 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; 16 through 18 years are the
preferred ages for vaccination.

3 Talk with your health care provider

Tell your vaccine 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 to a future visit.

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, fatigue, headache, muscle or joint pain, fever, chills, nausea, or diarrhea can happen after meningococcal B vaccine. 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.

What if there is a serious problem?

5

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 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. 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. There is a time limit to file a claim for compensation.

7 How can I learn more?

- · Ask your healthcare provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - -Call 1-800-232-4636 (1-800-CDC-INFO) or
- Visit CDC's www.cdc.gov/vaccines

Vaccine Information Statement (Interim)

Meningococcal B Vaccine



8/15/2019 | 42 U.S.C. § 300aa-26

Recombinant Zoster (Shingles) Vaccine: What You Need to Know

Many Vaccine Information Statement's are available in Spanish and other languages. See www.immunize.org/vis

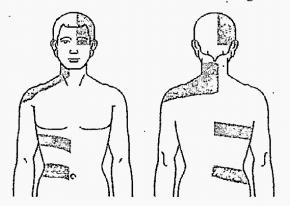
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1 Why get vaccinated?

Recombinant zoster (shingles) vaccine can prevent shingles.

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, usually with blisters. In addition to the rash, shingles can cause fever, headache, chills, or upset stomach. More rarely, shingles can lead to pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death.

The most common complication of shingles is long-term nerve pain called postherpetic neuralgia (PHN). PHN occurs in the areas where the shingles rash was, even after the rash clears up. It can last for months or years after the rash goes away. The pain from PHN can be severe and debilitating.



About 10 to 18% of people who get shingles will experience PHN. The risk of PHN increases with age. An older adult with shingles is more likely to develop PHN and have longer lasting and more severe pain than a younger person with shingles.

Shingles is caused by the varicella zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life. Shingles cannot be passed from one person to another, but the virus that causes shingles can spread and cause chickenpox in someone who had never had chickenpox or received chickenpox vaccine.

2 Recombinant shingles vaccine

Recombinant shingles vaccine provides strong protection against shingles. By preventing shingles, recombinant shingles vaccine also protects against PHN.

Recombinant shingles vaccine is the preferred vaccine for the prevention of shingles. However, a different vaccine, live shingles vaccine, may be used in some circumstances.

The recombinant shingles vaccine is recommended for adults 50 years and older without serious immune problems. It is given as a two-dose series.

This vaccine is also recommended for people who have already gotten another type of shingles vaccine, the live shingles vaccine. There is no live virus in this vaccine.

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

Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of recombinant shingles vaccine, or has any severe, life-threatening allergies.
- Is pregnant or breastfeeding.
- Is currently experiencing an episode of shingles.

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



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 recombinant shingles vaccine.

Your health care provider can give you more information.

4 Risks of a vaccine reaction

- A sore arm with mild or moderate pain is very common after recombinant shingles vaccine, affecting about 80% of vaccinated people. Redness and swelling can also happen at the site of the injection.
- Tiredness, muscle pain, headache, shivering, fever, stomach pain, and nausea happen after vaccination in more than half of people who receive recombinant shingles vaccine.

In clinical trials, about 1 out of 6 people who got recombinant zoster vaccine experienced side effects that prevented them from doing regular activities. Symptoms usually went away on their own in 2 to 3 days.

You should still get the second dose of recombinant zoster vaccine even if you had one of these reactions after the first dose.

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.

What if there is a serious problem?

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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 do not give medical advice.

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How can I learn more?

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Vaccine Information Statement Recombinant Zoster Vaccine



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