VACCINE INFORMATION STATEMENT

Serogroup B Meningococcal Vaccine (MenB): *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 disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and bacteremia or septicemia (infections of the blood). Meningococcal disease often strikes without warning—even people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *Neisseria meningitidis*, called "serogroups." Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants less 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*
- People at risk because of an outbreak in their community

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, amputations, nervous system problems, or severe scars from skin grafts.

Serogroup B meningococcal (MenB) vaccine can help prevent meningococcal disease caused by serogroup B. Other meningococcal vaccines are recommended to help protect against serogroups A, C, W, and Y.

2 Serogroup B Meningococcal Vaccines

Two serogroup B meningococcal vaccines have been licensed by the Food and Drug Administration.

These vaccines are recommended routinely for people 10 years or older who are at increased risk for serogroup B meningococcal infections, including:

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

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.

The recommended schedule depends on which vaccine you get:

- Bexsero® is given as **2 doses**, at least 1 month apart.
  or
- Trumenba® is given as **3 doses**, with the second dose 2 months after the first and the third dose 6 months after the first.

The same vaccine must be used for all doses.

3 Some people should not get these vaccines

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.** If you have ever had a life-threatening allergic reaction after a previous dose of serogroup B meningococcal vaccine, or if you have a severe allergy to any part of this vaccine, you should not get the vaccine. *Tell your healthcare provider if you any severe allergies that you know of, including a severe allergy to latex*. He or she can tell you about the vaccine's ingredients.
- **If you are pregnant or breastfeeding.** There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.
- **If you are not feeling well.** It is usually okay to get this vaccine when you have a mild illness, but you might be advised to come back when you feel better.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

More than half of the people who get serogroup B meningococcal vaccine have **mild problems** following vaccination. These reactions can last up to 3 to 7 days, and include:

- Soreness, redness, or swelling where the shot was given
- Tiredness or fatigue
- Headache
- Muscle or joint pain
- Fever or chills
- Nausea or diarrhea

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety**/

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within a few minutes to a few hours after the vaccination.

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your doctor.
- Reactions should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does 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.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information. 1-888-767-4687
- 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 website at **www.cdc.gov/vaccines**

42 U.S.C. § 300aa-26

AUTH: P. H. S., Act 42, Sect. 2126.