Patient Information about ERVEBO® (pronounced "er-VEE-boh") (Ebola Zaire Vaccine, Live)

Before you or your child get ERVEBO®, read this document and be sure you understand all of the information. Keep this document. You may need to read it again. If you have questions or side effects, ask the health care provider. This information does not take the place of talking about ERVEBO with the health care provider.

You or your child may be advised to get this vaccine in an emergency situation.

What is ERVEBO?

- ERVEBO is a vaccine to prevent disease caused by Zaire ebolavirus in individuals who are 12 months of age and older.
- This vaccine is given to help protect you or your child from getting Ebola virus disease caused by one type of Ebola virus (*Zaire ebolavirus*). This vaccine will not protect against disease caused by other types of Ebola virus.
- You or your child cannot get Ebola virus disease from ERVEBO.
- After getting ERVEBO, you or your child should continue to protect against exposure to Ebola virus.
- ERVEBO might not protect everyone who gets the vaccine.

What should I tell the health care provider before getting ERVEBO?

You should tell the health care provider if you or your child:

- have ever had an allergic reaction to a vaccine or medicine
- have ever had an allergic reaction to ERVEBO, rice protein or any of the ingredients in this
 vaccine
- are pregnant or breastfeeding
- think you or your child may be pregnant or are planning to have a baby
- have a weakened immune system or take medicines or treatments that might weaken the immune system
- have close contact with anyone who has a weakened immune system

How will I get ERVEBO?

ERVEBO is given as an injection.

What are the side effects of ERVEBO?

Serious allergic reactions have been observed after administration of ERVEBO. Tell the health care provider promptly about any unusual or severe symptoms that develop after getting this vaccine. Get medical care right away if you or your child have signs of an allergic reaction, which may include:

- wheezing or trouble breathing
- swelling of the face, lips, tongue, or other parts of the body
- generalized itching, redness, flushing or itchy bumps on the skin

Other side effects in individuals 18 years of age and older:

- Pain, swelling, or redness at the injection site
- Fever
- · Feeling tired
- Joint pain
- Muscle aches
- Headache
- Stomach pain

- Chills
- Abnormal sweating
- Nausea
- Skin rash (including blisters)
- Joint swelling
- Eating less than usual
- Mouth sores
- Vomiting

Certain white blood cell counts can become lower than normal after vaccination but are not associated with illness and go back to normal.

Most side effects go away within a few days. Joint pain and swelling may last for weeks, months, or years in some people. In some people, joint pain and swelling may come back after initially going away.

Side effects in individuals 12 months through 17 years of age:

- Pain, itching, swelling, or redness at the injection site
- Fever
- Headache
- Feeling tired
- Eating less than usual
- Muscle aches
- Crying
- Feeling dizzy
- Mouth sore

- Abdominal pain
- Vomiting
- Chills
- Diarrhea
- Joint pain
- Irritability
- Screaming
- Abnormal sweating
- Nausea

If you or your child have any side effect that bothers you or your child or does not go away, tell the doctor, pharmacist or nurse.

There may be other side effects that are not listed here.

Talk to the doctor, pharmacist or nurse with questions or concerns about possible side effects.

You may also report any side effects to Merck Sharp & Dohme LLC at 1-877-888-4231 or directly to Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov.

Other information

 ERVEBO may cause you or your child to have a positive test for Ebola, even if you or your child don't have the disease. Tell the health care provider that you or your child received ERVEBO. The health care provider might need to do a different test.

What is in ERVEBO?

Active ingredient: live Vesicular Stomatitis Virus in which the surface protein has been replaced with that of *Zaire ebolavirus*.

Inactive ingredients: recombinant human serum albumin, tromethamine (Tris) buffer.

This vaccine contains a trace amount of rice protein.

What if I have other questions?

- To learn more about ERVEBO, talk to the health care provider.
- Keep this information about ERVEBO. You might want to look at it again.

Manufactured by: Merck Sharp & Dohme LLC

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For patent information: www.msd.com/research/patent

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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