

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

## **ERVEBO®**

Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)

Read this carefully before you are vaccinated with **ERVEBO®**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ERVEBO®**.

### **What is ERVEBO® used for?**

- ERVEBO® is a vaccine for adults who are 18 years of age and older.
- ERVEBO® is given to protect you from getting Ebola virus disease caused by the Zaire Ebola virus, which is a type of Ebola virus. This vaccine will not protect you against the other types of Ebola virus or related Filoviruses, such as Sudan Ebola virus or Marburg virus
- Because ERVEBO® does not contain the whole Ebola virus, it cannot give you Ebola virus disease.

Your healthcare professional may recommend that you receive this vaccine in an emergency involving the spread of Ebola virus disease.

### **How does ERVEBO® work?**

The vaccine works by helping your body to make its own antibodies which can protect you against the Ebola Virus Disease caused by Zaire Ebola virus.

### **What is Ebola?**

- Ebola is a serious disease caused by a virus. If you get Ebola, it can kill you. People catch Ebola from people or animals who are infected with Ebola or who died from Ebola.
- You can catch Ebola from blood and body fluids like urine, stools, saliva, vomit, sweat, breast milk, semen and vaginal fluids of people who are infected with Ebola virus.
- You can also catch Ebola from things that have touched the blood or body fluids of a person or animal with Ebola (like clothes or objects in direct contact).
- Ebola is not spread through the air, water or food.

Your healthcare professional will talk to you and then together you can decide if you should receive this vaccine.

### **What are the ingredients in ERVEBO®?**

Medicinal ingredients: Living Vesicular Stomatitis Virus. The surface protein of the virus has been replaced with that of Zaire Ebola Virus (rVSVΔG-ZEBOV-GP).

One dose (1 mL) contains:

Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP<sup>1,2</sup> live, attenuated) ≥72 million pfu<sup>3</sup>

<sup>1</sup>Recombinant Vesicular Stomatitis Virus (rVSV) strain Indiana with a deletion of the VSV envelope glycoprotein (G) replaced with the Zaire Ebola Virus (ZEBOV) Kikwit 1995 strain surface glycoprotein (GP)

<sup>2</sup>Produced in Vero cells

<sup>3</sup>pfu= plaque-forming units

This product contains genetically modified organisms (GMOs).

This vaccine contains a trace amount of rice protein.

Non-medicinal ingredients: Recombinant human serum albumin, trometamol buffer, water for injections, hydrochloric acid, sodium hydroxide

### **What ERVEBO® looks like and contents of the pack:**

- ERVEBO® is a solution for injection
- ERVEBO® is a colorless to slightly brownish-yellow liquid
- ERVEBO® is available in a pack of 10 vials

### **Do not use ERVEBO® if:**

- are allergic to ERVEBO®, rice, or any of the other ingredients of this vaccine (listed in the section above: **“What are the ingredients in ERVEBO®?”**)

You should not receive ERVEBO® if any of the above apply to you. If you are not sure, talk to your healthcare professional.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you get ERVEBO®. Talk about any health conditions or problems you may have, including if you:**

#### Have had allergic reactions to vaccines or medicines

If you have ever had an allergic reaction to a vaccine or medicine, talk to your healthcare professional before you receive this vaccine.

#### Have a weak immune system

If your immune system is weak (which means your body is less able to fight off diseases), you might not be able to receive ERVEBO®. You might have a weak immune system if:

- you have HIV infection or AIDS,
- you are taking certain medicines that make your immune system weak such as immunosuppressants or corticosteroids,
- you have cancer or a blood problem that makes your immune system weak,
- a member of your family has a weak immune system.

If you think you might have a weak immune system, ask your healthcare professional if you should receive this vaccine. If you do get the vaccine and have a weak immune system, the vaccine may not work as well as in people with a normal immune system.

### Are in contact with vulnerable individuals

Tell your healthcare professional if in the 6 weeks after you receive ERVEBO® you might be in close contact with or in the same household as:

- babies who are less than 1 year old,
- someone who may be pregnant or breast-feeding,
- someone who has a weak immune system.

This is because you could pass on the virus in the vaccine to them through your body fluids.

### Plan to donate blood

- Do not donate blood for at least 6 weeks after you receive this vaccine.

### Are in contact with farm animals

Make sure your blood or body fluids do not come into close contact with farm animals for at least 6 weeks after you receive this vaccine. This is because of a possibility that you could pass on the virus in the vaccine to the animals.

### Have a fever (high temperature)

- If you have a fever (high temperature), you should talk to your healthcare professional before receiving ERVEBO®. The vaccination may have to be delayed until your fever is gone.
- A minor infection such as a cold should not be a problem but talk to your healthcare professional before receiving ERVEBO®.

### Have a bleeding disorder or bruise easily

- Tell your healthcare professional if you have a problem with bleeding or you bruise easily. ERVEBO® might make you bleed or bruise where the vaccine is injected.

### Take a test for Ebola after you receive ERVEBO®

- You may test positive for Ebola virus after you receive ERVEBO®. This does not mean that you have Ebola. Tell your healthcare professional that you have received ERVEBO®. Your healthcare professional might need to do another test.

### Are pregnant or breast-feeding

- You are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before you receive this vaccine. They will help you decide if you should receive ERVEBO®.
- Do not become pregnant for 2 months after you receive ERVEBO®. Women who are able to become pregnant should use an effective method of birth control. It is not known if ERVEBO® will harm you or your unborn baby. It is also not known if it can pass to your baby through your breast milk.
- If you might be in close contact with, or in the same household as someone who may be pregnant or breast-feeding during the 6 weeks after you receive ERVEBO®, tell your healthcare professional. This is because you could pass the vaccine to them through your body fluids.

### **Other warnings you should know about:**

This vaccine might not protect everyone who receives it and the length of time you are protected from Ebola infection by ERVEBO® is not known.

Continue to follow your healthcare professional's recommendations to protect yourself from Ebola infection after you get this vaccine.

#### In an area affected by Ebola:

While in an area affected by Ebola, it is important to avoid the following:

- Contact with blood and body fluids (such as urine, feces, saliva, sweat, vomit, breast milk, semen, and vaginal fluids).
- Items that may have come in contact with an infected person's blood or body fluids (such as clothes, bedding, needles, and medical equipment).
- Funeral or burial rituals that require handling the body of someone who died from Ebola.
- Contact with bats, apes and monkeys or with blood, fluids and raw meat prepared from these animals (bushmeat) or meat from an unknown source.
- Contact with semen from a man who had Ebola. You should follow safe sex practices until you know the virus is gone from the semen.

#### In case of rash:

If you get a rash where the skin is broken after receiving ERVEBO<sup>®</sup>, cover it until it heals. Put the used plasters and bandages in a sealed container, if possible, and throw them in the waste bin to make sure that people with a weak immune system or animals do not come into contact with the plasters and bandages.

**Tell your healthcare professional about all the medicines you take, have recently taken or might take including any drugs, vaccines, vitamins, minerals, natural supplements or alternative medicines.**

#### **The following may interact with ERVEBO<sup>®</sup>:**

No studies have looked at how other medicines or vaccines and ERVEBO<sup>®</sup> might interact with each other. Use of ERVEBO<sup>®</sup> with other vaccines is not recommended.

#### If you plan to receive blood or blood products

Do not receive this vaccine at the same time that you get blood or blood products. ERVEBO<sup>®</sup> might not work as well if you get blood or blood products 3 months before or up to 1 month after vaccination.

#### **How is ERVEBO<sup>®</sup> given?:**

##### **Usual dose:**

##### **Adult:**

ERVEBO<sup>®</sup> is given by a healthcare professional. It is given as a single injection (dose of 1 mL) into the muscle (in the top of your arm or the outside of your thigh).

If you have any further questions on the use of this vaccine, ask your healthcare professional.

##### **Children and adolescents**

It has not yet been established whether ERVEBO<sup>®</sup> can be used in children and adolescents younger than 18 years of age.

**Overdose:**

If you think you, or a person you are caring for, have received too much ERVEBO<sup>®</sup>, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

ERVEBO<sup>®</sup> is given as a single dose.

**What are possible side effects from using ERVEBO<sup>®</sup>?**

Like all vaccines, ERVEBO<sup>®</sup> can cause side effects, although not everybody gets them.

**Serious side effects:**

Serious side effects are rare. Get medical care right away if you have symptoms of an allergic reaction, which may include:

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

**Other side effects:**

Very common (may affect more than 1 in 10 people):

- Headache,
- Joint pain,
- Fever,
- Pain,
- Pain, swelling, or redness at the injection site.

Common (may affect up to 1 in 10 people):

- Nausea,
- Chills,
- Influenza like illness
- Muscle aches,
- Feeling tired.

Certain white blood cell counts can decrease below normal after vaccination but this decrease has not resulted in illness and the counts return to normal.

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

These are not all the possible side effects you may have when taking ERVEBO<sup>®</sup>. If you experience any side effects not listed here, tell your healthcare professional.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare worker.

### Reporting Suspected Side Effects for Vaccines

**For the general public:** Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Merck Canada Inc. cannot provide medical advice.

**For healthcare professional:** If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php>) and send it to your local Health Unit.

### Storage:

ERVEBO® should be stored, supplied and administered by a healthcare professional.

Keep out of reach and sight of children.

### If you want more information about ERVEBO®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare workers and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website [www.merck.ca](http://www.merck.ca), or by calling 1-800-567-2594.

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