Pack size of 10 vials.

6.6 Special precautions for disposal and other handling

- The vaccine is stored frozen at -80°C to -60°C and should be removed from the freezer and thawed in less than 4 hours until no visible ice is present. Do not thaw the vial in a refrigerator as it is not guaranteed that the vial will thaw in less than 4 hours. The thawed vial should then be gently inverted several times prior to withdrawal with the syringe. The vaccine should appear as a colourless to slightly brownish-yellow liquid with no particulates visible. Discard the vaccine if particulates are present.
- Withdraw the entire content of the vaccine from the vial using a sterile needle and syringe.

If feasible, the waste liquid from eye washes should be collected and decontaminated before discarding into the drain.

Any unused vaccine or waste material should be disposed in compliance with the institutional guidelines for genetically modified organisms or biohazardous waste, as appropriate.

If breakage/spillage were to occur, disinfectants such as aldehydes, alcohols and detergents are proven to reduce viral infection potential after only a few minutes.

7. MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/19/1392/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 November 2019
Date of latest renewal: 15 September 2020

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

Burgwedel Biotech GmbH
Im Langen Felde 5
30938 Burgwedel
Germany

Name and address of the manufacturer(s) responsible for batch release

Burgwedel Biotech GmbH
Im Langen Felde 5
30938 Burgwedel
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

- **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

SOLUTION FOR INJECTION IN VIAL - PACK OF 10

1. NAME OF THE MEDICINAL PRODUCT

Ervebo solution for injection
Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One dose (1 mL):
Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live attenuated) ≥72 million pfu

3. LIST OF EXCIPIENTS

Recombinant human serum albumin, trometamol buffer, water for injections, hydrochloric acid, sodium hydroxide

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
10 vials

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store and transport frozen at -80°C to -60°C.
Do not thaw the vial in a refrigerator. Do not refreeze.
Keep the vial in the outer carton to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

This product contains genetically modified organisms.
Any unused vaccine or waste material should be disposed of in compliance with the institutional guidelines for genetically modified organisms or biohazardous waste, as appropriate.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/19/1392/001 - pack of 10

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Ervebo solution for injection
rVSVΔG-ZEBOV-GP, live
IM

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 dose

6. OTHER

This product contains GMO.

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Ervebo Solution for injection
Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you or your child is vaccinated because it contains important information for you or your child.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your healthcare worker.
- If you or your child gets any side effects, talk to your healthcare worker. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ervebo is and what it is used for

- Ervebo is a vaccine for people who are 1 year of age and older.
- Ervebo is given to protect people from getting Ebola virus disease caused by the Zaire Ebola virus, which is a type of Ebola virus. This vaccine will not protect against the other types of Ebola virus.
- Because Ervebo does not contain the whole Ebola virus, it cannot give people Ebola virus disease.

Your healthcare worker may recommend receiving this vaccine in an emergency involving the spread of Ebola virus disease.

What is Ebola?
- Ebola is a serious disease caused by a virus. If people get Ebola, it can kill them. People catch Ebola from people or animals who are infected with Ebola or who died from Ebola.
- People 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.
- People 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 worker will talk to you and then together you can decide if you or your child should receive this vaccine.

2. What you need to know before you or your child receives Ervebo

Do not receive Ervebo if you:
- are allergic to Ervebo, rice, or any of the other ingredients of this vaccine (listed in section 6).

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

Warnings and precautions
This vaccine might not protect everyone who receives it and the length of time you are protected from Ebola by Ervebo is not known.

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

Hand washing:

Washing your hands correctly is the most effective way to prevent the spread of dangerous germs, like Ebola virus. It reduces the number of germs on the hands and so reduces their spread from person to person.

Proper hand washing methods are described below;
- Use soap and water when hands are soiled with dirt, blood, or other body fluids. There is no need to use antimicrobial soaps for washing hands.
- Use alcohol-based hand sanitiser when hands are not dirty. Do not use alcohol-based hand sanitiser when hands are soiled with dirt, blood, or other body fluids.

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, faeces, 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, 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.

Taking care of children that have received Ervebo:

For at least 6 weeks after children receive this vaccine, it is important that you wash your hands thoroughly after you have been in contact with blood or body fluids of vaccinated children. If possible clean soiled nappies with appropriate detergents/disinfectants or if using disposable nappies, seal them in double plastic bag and dispose of them in the household waste.

Talk to your healthcare worker before you receive Ervebo 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 worker 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 worker 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 worker 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 worker 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 worker before receiving Ervebo.

Have a bleeding disorder or bruise easily
- Tell your healthcare worker if you have a problem with bleeding or you bruise easily. Ervebo might make you bleed or bruise where the vaccine is injected.

Testing 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 worker that you have received Ervebo. Your healthcare worker might need to do another test.

Children younger than 1 year of age
If your child is under 1 year old, talk to your healthcare worker. It is not known if this medicine is safe and works in children under 1 year old.

Other medicines and Ervebo
Tell your healthcare worker if you are taking, have recently taken or might take any other medicines or vaccines.

No studies have looked at how other medicines or vaccines and Ervebo might interact with each other. Use of Ervebo 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 might not work as well if you get blood or blood products 3 months before or up to 1 month after vaccination.

Pregnancy and breast-feeding
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare worker 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 the mother or the unborn baby. It is also not known if it can pass to the baby through 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 worker. This is because you could pass the vaccine to them through your body fluids.

Ervebo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium–free'.

3. How Ervebo is given

Ervebo is given by a healthcare worker. It is given as a single injection (dose of 1 mL) in the top of the arm or the outside of the thigh.

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

4. Possible side effects

Like all vaccines, Ervebo can cause side effects, although not everybody gets them.

Serious side effects:
Serious side effects are rare. Get medical care right away if you or your child has 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 in adults 18 years and older:
Very common (may affect more than 1 in 10 people):
- Headache,
- Joint pain,
- Muscle aches,
- Fever,
- Feeling tired,
- Chills,
- Pain, swelling, or redness at the injection site,
- Eating less than usual,
- Stomach pain.

Common (may affect up to 1 in 10 people):
- Nausea,
- Skin rash,

- Joint swelling,
- Excessive sweating,
- Feeling dizzy,
- Mouth sores,
- Itching at the injection site.

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.

Side effects in children and adolescents 1 to 17 years of age:
Very common (may affect more than 1 in 10 people):
- Headache,
- Eating less than usual,
- Muscle aches,
- Fever,
- Feeling tired,
- Chills,
- Pain where your child got this vaccine,
- Stomach pain.

Common (may affect up to 1 in 10 people):
- Joint pain,
- Nausea,
- Feeling dizzy,
- Excessive sweating,
- Mouth sores,
- Crying,
- Swelling or itching where your child got this vaccine.

Uncommon (may affect up to 1 in 100 people):
- Redness where your child got this vaccine.

Tell your healthcare worker if you or your child gets any of the side effects listed above.

Reporting of side effects
If you get any side effects, talk to your healthcare worker. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ervebo

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the vial label and the outer carton after 'EXP'. The expiry date refers to the last day of that month.
- Store and transport frozen at -80°C to -60°C.
- After thawing, the vaccine should be used immediately. However, once thawed, the vaccine can be stored for up to 14 days at 2°C to 8°C before use. Discard the vaccine if it is not used by the end of 14 days. Once thawed, the vaccine cannot be re-frozen.
- Upon removal from the freezer, the product should be marked with both the date that it was taken out of the freezer and also a new discard date (in place of the labelled expiry date).

- Keep the vial in the outer carton in order to protect from light.
- Do not use this vaccine if you notice particles in the liquid.
- Do not throw away any medicines via wastewater or household waste. Ask your healthcare worker how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ervebo contains
The active substance is a 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[1,2] live, attenuated) ≥72 million pfu[3]
[1]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)
[2]Produced in Vero cells
[3]pfu= plaque-forming units

This product contains genetically modified organisms (GMOs).
This vaccine contains a trace amount of rice protein.
This vaccine contains less than 1 mmol (23 mg) of sodium per dose.

The other excipients are 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 colourless to slightly brownish-yellow liquid.
- Ervebo is available in a pack of 10 vials.

Marketing Authorisation Holder
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2031 BN Haarlem
The Netherlands

Manufacturer
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in MM/YYYY

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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The following information is intended for healthcare professionals only:

Standard precautions when caring for patients with known or suspected Ebola disease
Vaccination with Ervebo does not eliminate the necessity of standard precautions when caring for patients with known or suspected Ebola disease. **All healthcare workers, and other ancillary providers who have been vaccinated, should not alter their practices with regard to safe injection, hygiene, and personal protective equipment (PPE) after vaccination.**

Standard precautions, as outlined by WHO, include the following:
- Basic hand hygiene
- Respiratory hygiene
- Use of PPE (to block splashes or other contact with infected materials)
- Safe injection practices
- Safe burial practices

Healthcare workers caring for patients with suspected or confirmed Ebola virus should apply extra infection control measures to prevent contact with the patient's blood and body fluids and contaminated surfaces or materials such as clothing and bedding. When in close contact (within 1 metre) of patients with Ebola Virus Disease, healthcare workers should wear face protection (a face shield or a medical mask and goggles), a clean, non-sterile long-sleeved gown, and gloves (sterile gloves for some procedures).

Laboratory workers are also at risk. Samples taken from humans and animals for investigation of Ebola infection should be handled by trained staff and processed in suitably equipped laboratories.

Vaccine administrators should counsel vaccinees to continue to protect themselves with the following measures:
- Hand washing
- Avoid contact with blood and body fluids
- Safe burial practices
- Safe sex

- Avoid contact with bats and non-human primates or blood, fluids and raw meat prepared from these animals (bushmeat) or meat from an unknown source.

Instructions on the handling of the vaccine before administration

- Ervebo is stored frozen at -80°C to -60°C and should be removed from the freezer and thawed in less than 4 hours until no visible ice is present. Do not thaw the vial in a refrigerator as it is not guaranteed that the vial will thaw in less than 4 hours. The thawed vial should then be gently inverted several times prior to withdrawal with the syringe.
- After thawing, Ervebo should be used immediately; however, in-use stability data have demonstrated that once thawed, the vaccine can be stored for up to 14 days at 2°C to 8°C prior to use. At the end of 14 days, the vaccine should be used or discarded. Upon removal from the freezer, the product should be marked with both the date that it was taken out of the freezer and also a new discard date (in place of the labelled expiry date). Once thawed, the vaccine cannot be re-frozen.
- Ervebo is a colourless to slightly brownish-yellow liquid. Discard the vaccine if particulates are present.
- Ervebo should be administered intramuscularly. Do not inject the vaccine intravascularly. No data are available for administration via the subcutaneous or intradermal routes.
- Ervebo should not be mixed in the same syringe with any other vaccines or medicinal products.
- Withdraw the entire content of Ervebo from the vial using a sterile needle and syringe. The preferred injection site is the deltoid area of the non-dominant arm or in the higher anterolateral area of the thigh. Cover the injection site with gauze or bandage (e.g. any adhesive bandage or gauze and tape) that provides a physical barrier to protect against direct contact with vesicle fluid. The bandage may be removed when there is no visible fluid leakage.
- Any unused vaccine or waste material should be disposed of in compliance with the institutional guidelines for genetically modified organisms or biohazardous waste, as appropriate. If breakage/spillage were to occur, disinfectants such as aldehydes, alcohols and detergents are proven to reduce viral infection potential after only a few minutes. If feasible, the waste liquid from eye washes should be collected and decontaminated before discarding into the drain.