Package leaflet: Information for the user

Zabdeno suspension for injection
Ebola vaccine (Ad26.ZEBOV-GP [recombinant])

▼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.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zabdeno is and what it is used for

What is Zabdeno
Zabdeno is a vaccine used to protect against Ebola virus disease in the future.
It is given to people aged 1 year and older who may possibly come into contact with Ebola virus.

Zabdeno is given as the first dose of a 2-dose course of vaccinations to protect you from getting Ebola virus disease caused by the *Zaire ebolavirus*, which is a type of Filovirus. This vaccine will not protect you against the other types of Filovirus.

Because Zabdeno does not contain the whole Ebola virus, it cannot give you Ebola virus disease.

The 2-dose course of vaccinations consists of:
- a first dose of Zabdeno vaccine,
- followed around 8 weeks later by a dose with Mvabea vaccine.

Even after you have had the course of Zabdeno and Mvabea vaccination you should be **very careful** not to come into contact with Ebola virus. As with all vaccinations, the vaccination course may not fully protect everyone from Ebola virus disease.

The Zabdeno and Mvabea 2-dose course of vaccinations should be used according to official recommendations.

What is Ebola
- Ebola is a serious disease caused by a virus. People catch Ebola from people or animals who are infected with Ebola virus 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.

Ebola virus disease usually causes a high fever – and it can stop the blood from clotting, causing severe bleeding ('severe haemorrhagic fever'). This can lead to serious illness, and in some cases **death**.

- First signs and symptoms may be fever, feeling tired, weak or dizzy, and muscle aches.
- Later signs and symptoms may include bleeding under the skin, into organs in the body such as the liver or kidneys and from the mouth, eyes or ears. Some people get severe diarrhea, sudden drop in blood pressure or blood flow to the organs in the body (shock) which may cause serious and permanent damage to these organs, severe confusion (delirium), fits (seizures), kidney failure and coma.

Talk to your doctor, pharmacist or nurse first to decide if you should be given this vaccine.

How the vaccine works
The Zabdeno and Mvabea 2-dose vaccine course stimulates the body's natural defences (immune system). The vaccine works by causing the body to produce its own protection (antibodies) against the virus that causes the Ebola infection. This will help to protect against Ebola virus disease in the future.

2. What you need to know before you or your child are given Zabdeno

To make sure that the vaccination course is suitable for you or your child, it is important to tell your doctor, pharmacist or nurse if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor, pharmacist or nurse to explain.

Do not have the vaccine if

- you or your child have ever had a severe allergic reaction to any of the active substances or any of the other ingredients listed in section 6.

If you are not sure, talk to your doctor, pharmacist or nurse before you are given the vaccine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Zabdeno if you or your child:

- have ever had a severe allergic reaction after any other vaccine injection,
- have ever fainted, after having an injection,
- have a problem with bleeding or you bruise easily,
- currently have a fever or an infection,
- are taking medicines that weaken the immune system, such as high-dose corticosteroids (such as prednisone) or chemotherapy (cancer medicines),
- have a weak immune system – for example, due to HIV infection or an illness that runs in the family ('genetic disorder').

If any of the above apply to you or your child (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Zabdeno.

If you are at high risk of being in contact with the Ebola virus, a booster vaccination with Zabdeno may be recommended for you or your child. Talk to your doctor, pharmacist or nurse if this applies to you or your child.

If you or your child only has one of the vaccines, Zabdeno or Mvabea, it may give less protection from Ebola virus disease than having a course of both vaccines.

As with all vaccines, the Zabdeno and Mvabea 2-dose course of vaccination may not fully protect everyone from Ebola virus disease and it is not known how long you will be protected.

- **People who have been given the 2-dose course of vaccination should still take precautions to avoid coming into contact with Ebola virus.**

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.

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 the virus is gone from the semen. Talk to your doctor, pharmacist or nurse for advice about how long to maintain safe sex practices.

Children younger than 1 year of age
Zabdeno must not be used in children younger than 1 year of age.

Other medicines and Zabdeno
Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take, any other medicines or vaccines.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before having this vaccine if you or your child is pregnant or breast-feeding. Also do this if you think you or your child may be pregnant or are planning to have a baby.

Driving and using machines
Zabdeno has no known effect on the ability to drive and use machines.

Zabdeno contains Sodium
Zabdeno contains less than 1 mmol sodium (23 mg) per dose of 0.5 mL, that is to say essentially 'sodium-free'.

Zabdeno contains ethanol (alcohol)
This medicine contains .002 mg of alcohol (ethanol) per dose of 0.5 mL. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How Zabdeno is given

Your doctor or nurse will inject the vaccine into a muscle (intramuscular injection) in the upper arm or thigh.

Zabdeno must not be injected into a blood vessel.

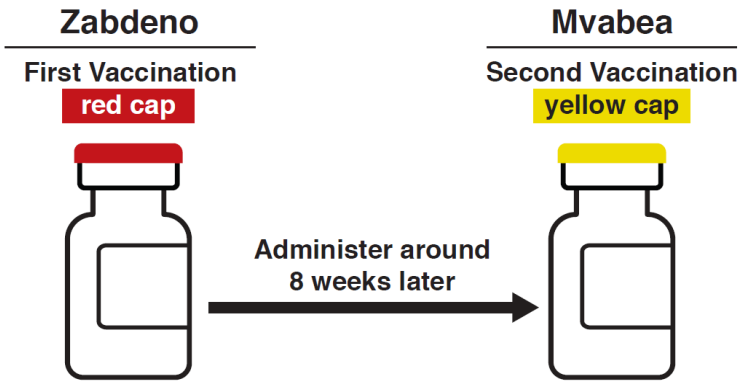
The 2-dose course of vaccination consists of:
- a dose of Zabdeno vaccine,
- followed around 8 weeks later by a dose of Mvabea vaccine.

Your doctor will tell you the date for the second vaccine.

How much vaccine will you or your child get

Primary vaccination

- First vaccination with Zabdeno – red cap vial (0.5 mL).
- Second vaccination with Mvabea – yellow cap vial (0.5 mL), given around 8 weeks after the first vaccination with Zabdeno.



Booster vaccination with Zabdeno (an extra dose of Zabdeno to increase or renew the effect of an earlier Zabdeno and Mvabea 2-dose course of vaccination)

- The booster vaccination is recommended for you or your child if you are at high risk of being in contact with the Ebola virus and you completed the 2-dose course of vaccination more than 4 months ago.
- Ask your doctor if you or your child should consider getting the booster vaccination.

During and after the injection of the vaccine, the doctor will watch over you or your child for around 15 minutes or longer as necessary in case of a severe allergic reaction.

Instructions for preparing the vaccine – for medical and healthcare professionals – are included at the end of the leaflet.

If you have an unintended or accidental injection of Zabdeno or Mvabea

- If you or your child are accidently given Mvabea as the first vaccination – you will get Zabdeno as the second vaccination around 8 weeks later.
- If you or your child are accidently given Zabdeno as the first and the second vaccination – you will get Mvabea around 8 weeks after the second vaccination with Zabdeno.
- If you or your child are accidently given Mvabea as the first and the second vaccination – you will get Zabdeno around 8 weeks after the second vaccination with Mvabea.
- If you or your child have not been given Mvabea around 8 weeks after vaccination with Zabdeno – talk to your doctor, pharmacist or nurse about getting the second vaccination with Mvabea.

If you miss an appointment for vaccination of Zabdeno or Mvabea

- If you miss an appointment, tell your doctor and arrange another visit.
- If you miss a scheduled injection, you may not be fully protected from Ebola virus.
- If you have any further questions on the use of this vaccine, ask your doctor.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them. Most of the side effects happen within 7 days of getting the injection.

The following side effects can happen in adults.

Very common (may affect more than 1 in 10 people)
- pain, warmth, or swelling where the injection is given
- feeling very tired
- headache or muscle ache
- joint pain
- chills

Common (may affect up to 1 in 10 people)
- being sick (vomiting)
- itching where the injection is given
- generalised itching
- fever

Uncommon (may affect up to 1 in 100 people)
- feeling dizzy
- redness and skin hardness where the injection is given

The following side effects can happen in children and young people 1 to 17 years of age.

Very common (may affect more than 1 in 10 people)
- pain where the injection is given
- decreased activity
- decreased appetite
- feeling irritable
- feeling very tired

Common (may affect up to 1 in 10 people)
- swelling, itching or redness where the injection is given
- being sick (vomiting)
- feeling sick (nausea)
- joint pain
- muscle ache
- fever

Rare (may affect up to 1 in 1000 people)
- seizures (fits) with a fever in young children

Most of these side effects are mild to moderate in intensity and are not long-lasting.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via https://www.janssen.com/contact-us. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zabdeno

Keep this vaccine out of the sight and reach of children.

Information about storage, expiry, and use and handling are described in the section intended for healthcare professionals at the end of the leaflet.

Your doctor or pharmacist is responsible for storing this vaccine and disposing of any unused product correctly.

6. Contents of the pack and other information

What Zabdeno contains
One dose (0.5 mL) contains:

- The active substance is Adenovirus type 26 encoding the *Zaire ebolavirus* Mayinga variant glycoprotein*, not less than 8.75 $\log_{10}$ infectious units
  * Produced in PER.C6 cells and by recombinant DNA technology.

  This product contains genetically modified organisms (GMOs).

- The other ingredients (excipients) are disodium edetate, ethanol, histidine hydrochloride monohydrate, polysorbate-80, sodium chloride, sucrose, water for injections and sodium hydroxide (for pH adjustment).

What Zabdeno looks like and contents of the pack
Zabdeno is a suspension in a single-dose glass vial (0.5 mL) with a rubber stopper and red cap.

Colourless to slightly yellow, clear to very opalescent suspension.

Zabdeno is available in a pack containing 20 single-dose vials.

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This leaflet was last revised in 09/2022.

This vaccine has been authorised under 'exceptional circumstances'. This means that for scientific reasons it has been impossible to get complete information on this medicine.
The European Medicines Agency will review any new information on this vaccine every year and this leaflet will be updated as necessary.

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

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

The following information is intended for healthcare professionals only:
- As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of Zabdeno. Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.
- Zabdeno must not be mixed with other medicinal products in the same syringe.
- Zabdeno must not be administered by intravascular injection under any circumstances.
- Immunisation should be carried out by intramuscular (IM) injection preferably in the upper arm in the region of the deltoid or in the thigh.
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to injection with a needle. Procedures should be in place to prevent injury from falling and to manage syncopal reactions.

Instructions for administration and handling
Zabdeno is a colourless to slightly yellow, clear to very opalescent suspension. The vaccine should be inspected visually for particulate matter and discolouration prior to administration. The vial should be inspected visually for cracks or any abnormalities, such as evidence of tampering prior to administration. If there are signs of any of these, do not administer the vaccine.

Once the vaccine has been removed from the freezer and thawed, use immediately or store in a refrigerator at 2°C to 8°C (see section 6.4). Once removed from the refrigerator for administration, it should be used immediately.

Gently mix the contents of the vial by swirling for 10 seconds. Do not shake. Use a sterile needle and sterile syringe to extract the entire contents from the vial for administration.

Use a separate sterile needle and syringe for each individual. It is not necessary to change needles between drawing up the vaccine from a vial and injecting it into a recipient, unless the needle has been damaged or contaminated. Any remaining content in the vial should be discarded.

Any unused medicinal product or waste material should be disposed of in accordance to local requirements. Potential spills should be disinfected with agents with viricidal activity against adenovirus.

Information about storage
Do not use this vaccine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Transport frozen at -25°C to -15°C. Upon receipt, the product can be stored as indicated below:

Store in a freezer at -85°C to -55°C at the distributor in case of stockpiling. The expiry date for storage at -85°C to -55°C is printed on the vial and outer carton after EXP.

The vaccine can also be stored by the distributor or end user in a freezer at -25°C to -15°C for a single period of up to 20 months. Upon removal from the -85°C to -55°C freezer, the new expiry date must be written by the distributor or end user on the outer carton and the vaccine should be used or discarded at the end of the 20 months. This new expiry date should not exceed the original expiry date (EXP). The original expiry date should be made unreadable.

The vaccine can also be stored by the distributor or end user in a refrigerator at 2°C to 8°C for a single period of up to 8 months. Upon moving the product to 2°C to 8°C storage, the discard date must be written by the distributor or end user on the outer carton and the vaccine should be used or discarded at the end of the 8 months period. This discard date should not exceed the original expiry date (EXP), or the new expiry date assigned for the -25°C to -15°C storage condition. The original expiry date and/or the new expiry date assigned for the -25°C to -15°C storage condition should be made unreadable.

Once thawed, the vaccine cannot be refrozen.

The vial must be kept in the original package in order to protect from light and to track the expiry or discard date for the different storage conditions.