

Package leaflet: Information for the user

Mvabea suspension for injection Ebola vaccine (MVA-BN-Filo [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 Mvabea is and what it is used for
2. What you need to know before you or your child are given Mvabea
3. How Mvabea is given
4. Possible side effects
5. How to store Mvabea
6. Contents of the pack and other information

1. What Mvabea is and what it is used for

What is Mvabea

Mvabea 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.

Mvabea is given as the second 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 Mvabea 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 Mvabea

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.
- you or your child have ever had a severe allergic reaction to chicken or eggs or an antibiotic known as ‘gentamicin’.

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 Mvabea 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 Mvabea.

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 have 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

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

Other medicines and Mvabea

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

Mvabea has no known effect on the ability to drive and use machines.

Mvabea contains Sodium

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

3. How Mvabea is given

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

Mvabea must not be injected into a blood vessel.

The 2-dose course of vaccination consists of:

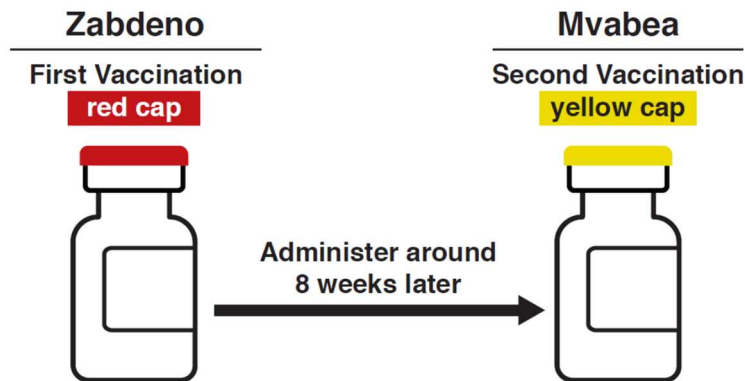
- a dose of Zabdeno vaccine,
- followed around 8 weeks later by a dose of Mvabea vaccine.

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 accidentally given Mvabea as the first vaccination – you will get Zabdeno as the second vaccination around 8 weeks later.
- If you or your child are accidentally 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 accidentally 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
- muscle ache
- joint pain

Common (may affect up to 1 in 10 people)

- being sick (vomiting)
- itching where the injection is given

Uncommon (may affect up to 1 in 100 people)

- redness and skin hardness where the injection is given
- generalised itching

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
- feeling very tired

Common (may affect up to 1 in 10 people)

- swelling, itching or redness where the injection is given
- fever
- chills
- muscle ache
- joint pain

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 Mvabea

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 Mvabea contains

One dose (0.5 mL) contains:

- The active substance is Modified Vaccinia Ankara Bavarian Nordic Virus* encoding the:
 - *Zaire ebolavirus* Mayinga variant glycoprotein (GP)
 - *Sudan ebolavirus* Gulu variant GP

- *Tai Forest ebolavirus* nucleoprotein
- *Marburg marburgvirus* Musoke variant GP

Not less than 0.7×10^8 infectious units

* Produced in chicken embryo fibroblast cells and by recombinant DNA technology.

This product contains genetically modified organisms (GMOs).

This vaccine contains trace residues of gentamicin (see section 2).

- The other ingredients (excipients) are sodium chloride, trometamol, water for injections and hydrochloric acid (for pH adjustment).

What Mvabea looks like and contents of the pack

Mvabea is a suspension in a single-dose glass vial (0.5 mL) with a rubber stopper and yellow cap.

Light yellow, clear to milky suspension.

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

Marketing Authorisation Holder

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

Manufacturer

Janssen Biologics B.V.
Einsteinweg 101
2333 CB Leiden
The Netherlands

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

België/Belgique/Belgien

Janssen-Cilag NV
Tel/Tél: +32 14 64 94 11
janssen@jacbe.jnj.com

Lietuva

UAB "JOHNSON & JOHNSON"
Tel: +370 5 278 68 88
lt@its.jnj.com

България

„Джонсън & Джонсън България“ ЕООД
Тел.: +359 2 489 94 00
jjsafety@its.jnj.com

Luxembourg/Luxemburg

Janssen-Cilag NV
Tél/Tel: +32 14 64 94 11
janssen@jacbe.jnj.com

Česká republika

Janssen-Cilag s.r.o.
Tel: +420 227 012 227

Magyarország

Janssen-Cilag Kft.
Tel.: +36 1 884 2858
janssenhu@its.jnj.com

Danmark

Janssen-Cilag A/S
Tlf: +45 4594 8282
jacdk@its.jnj.com

Malta

AM MANGION LTD
Tel: +356 2397 6000

Deutschland

Janssen-Cilag GmbH
Tel: +49 2137 955 955
jancil@its.jnj.com

Eesti

UAB "JOHNSON & JOHNSON" Eesti filiaal
Tel: +372 617 7410
ee@its.jnj.com

Ελλάδα

Janssen-Cilag Φαρμακευτική Α.Ε.Β.Ε.
Τηλ: +30 210 80 90 000

España

Janssen-Cilag, S.A.
Tel: +34 91 722 81 00
contacto@its.jnj.com

France

Janssen-Cilag
Tél: 0 800 25 50 75 / +33 1 55 00 40 03
medisource@its.jnj.com

Hrvatska

Johnson & Johnson S.E. d.o.o.
Tel: +385 1 6610 700
jjsafety@JNJCR.JNJ.com

Ireland

Janssen Sciences Ireland UC
Tel: +353 1 800 709 122

Ísland

Janssen-Cilag AB
c/o Vistor hf.
Sími: +354 535 7000
janssen@vistor.is

Italia

Janssen-Cilag SpA
Tel: 800.688.777 / +39 02 2510 1
janssenita@its.jnj.com

Κύπρος

Βαρνάβας Χατζηπαναγής Λτδ
Τηλ: +357 22 207 700

Latvija

UAB "JOHNSON & JOHNSON" filiāle Latvijā
Tel: +371 678 93561
lv@its.jnj.com

Africa Countries

To contact us, please visit our website <https://www.janssen.com/contact-us>

Nederland

Janssen-Cilag B.V.
Tel: +31 76 711 1111
janssen@jacnl.jnj.com

Norge

Janssen-Cilag AS
Tlf: +47 24 12 65 00
jacno@its.jnj.com

Österreich

Janssen-Cilag Pharma GmbH
Tel: +43 1 610 300

Polska

Janssen-Cilag Polska Sp. z o.o.
Tel.: +48 22 237 60 00

Portugal

Janssen-Cilag Farmacêutica, Lda.
Tel: +351 214 368 600

România

Johnson & Johnson România SRL
Tel: +40 21 207 1800

Slovenija

Johnson & Johnson d.o.o.
Tel: +386 1 401 18 00
Janssen_safety_slo@its.jnj.com

Slovenská republika

Johnson & Johnson, s.r.o.
Tel: +421 232 408 400

Suomi/Finland

Janssen-Cilag Oy
Puh/Tel: +358 207 531 300
jacfi@its.jnj.com

Sverige

Janssen-Cilag AB
Tfn: +46 8 626 50 00
jacse@its.jnj.com

United Kingdom (Northern Ireland)

Janssen Sciences Ireland UC
Tel: +44 1 494 567 444

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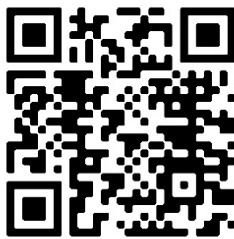
This vaccine has been authorised under ‘exceptional circumstances’. This means that for scientific reasons it has been impossible to get complete information on this medicine. The European Medicines Agency will review any new information on this vaccine every year and this leaflet will be updated as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

Scan the QR code below (also available on the carton and QR card) to get the electronic package leaflet.



Or visit the URL: www.janssenbolavaccine.com

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 Mvabea. Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.
- Mvabea must not be mixed with other medicinal products in the same syringe.
- Mvabea 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

Mvabea is a light yellow, clear to milky 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 vaccinia virus.

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 7 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 7 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 1 month. 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 1 month 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.