

## **Package leaflet: Information for the patient**

### **Evkeeza 150 mg/ml concentrate for solution for infusion** evinacumab

▼ 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 start using this medicine - 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Evkeeza is and what it is used for
2. What you need to know before you are given Evkeeza
3. How Evkeeza is given
4. Possible side effects
5. How to store Evkeeza
6. Contents of the pack and other information

#### **1. What Evkeeza is and what it is used for**

##### **What Evkeeza is**

Evkeeza contains the active substance evinacumab. It is a type of medicine called a 'monoclonal antibody'. Monoclonal antibodies are proteins that attach to other substances in the body.

##### **What Evkeeza is used for**

Evkeeza is used to treat adults and children aged 6 months and older with very high cholesterol caused by a condition called 'homozygous familial hypercholesterolaemia'. Evkeeza is used with a low-fat diet and other medicines to bring down cholesterol levels.

Homozygous familial hypercholesterolaemia runs in families and it is usually passed down by both father and mother.

People with this condition have extremely high levels of LDL-cholesterol ('bad cholesterol') from birth. Such high levels can lead to heart attacks, heart valve disease or other problems at an early age.

##### **How does Evkeeza work?**

Evinacumab, the active substance in Evkeeza, attaches to a protein in the body called ANGPTL3 and blocks its effects. ANGPTL3 is involved in controlling the production of cholesterol, and blocking its effect reduces the production of cholesterol. In this way, Evkeeza can lower blood levels of LDL-cholesterol and so prevent problems caused by high LDL-cholesterol levels.

## **2. What you need to know before you are given Evkeeza**

### **You should not be given Evkeeza if:**

- you are allergic to evinacumab or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor or nurse before you are given Evkeeza.

### **Look out for serious side effects**

Evkeeza can cause serious allergic reactions.

- Tell your doctor or nurse immediately if you get any symptoms of a severe allergic reaction. The symptoms are listed in “Serious side effects” in section 4.

### **Children**

Evkeeza is not recommended for children below the age of 6 months because there is not yet enough information on its use in this group of patients.

### **Other medicines and Evkeeza**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

### **Pregnancy and contraception**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

- Evkeeza may harm your unborn baby.
- Tell your doctor immediately if you become pregnant while you are being treated with Evkeeza.

If you are able to become pregnant, you should use effective contraception to avoid becoming pregnant.

- use effective contraception while you are being treated with Evkeeza and
- use effective contraception for at least 5 months after the last dose of Evkeeza.

Talk to your doctor about the best contraception method for you during this time.

### **Breast-feeding**

- If you are breast-feeding or plan to breast-feed, ask your doctor for advice before you are given this medicine.
- It is not known if Evkeeza passes into the breast milk.

### **Driving and using machines**

It is possible that Evkeeza could make you feel dizzy and tired and may affect your ability to ride a bike, drive, or use any tools or machines. If you think you are affected, do not ride a bike, drive, or use machines and tools, and tell your doctor (see section 4).

### **Evkeeza contains proline**

This medicine contains 30 mg of proline in each ml. Proline may be harmful for patients with hyperprolinaemia, a rare genetic disorder in which proline builds up in the body. If you (or your child) have hyperprolinaemia, do not use this medicine unless your doctor has recommended it.

### **Evkeeza contains polysorbate 80**

This medicine contains 1 mg of polysorbate 80 in each ml. Polysorbates may cause allergic reactions. Tell your doctor if you (or your child) have any known allergies.

### **3. How Evkeeza is given**

#### **How much Evkeeza is given**

Your doctor will work out how much of the medicine to give you. The amount will depend on your body weight.

- The recommended dose is 15 milligrams for every kilogram you weigh.
- You will be given the medicine around once a month.

#### **How Evkeeza is given**

Evkeeza is usually given by a doctor or nurse. It is given as a drip into a vein ('intravenous infusion') over 60 minutes.

#### **If you miss your dose of Evkeeza**

If you have missed an appointment to receive Evkeeza, talk to your doctor or nurse as soon as possible.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **Serious side effects**

##### **Severe allergic reactions** (uncommon: may affect up to 1 in 100 people)

Tell your doctor or nurse immediately if you get any of the following symptoms of a severe allergic reaction (anaphylactic reaction). The drip will be stopped immediately and you may need to take other medicines to control the reaction:

- swelling – mainly of the lips, tongue or throat, which makes it difficult to swallow or breathe
- breathing problems or wheezing
- feeling dizzy or fainting
- rash, hives
- itching.

#### **Other side effects**

Tell your doctor or nurse if you notice any of the following side effects:

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

- symptoms of the common cold, such as runny nose (nasopharyngitis).

##### **Common** (may affect up to 1 in 10 people)

- feeling dizzy
- sore throat or sinus infection (upper respiratory tract infection)
- feeling sick (nausea)
- stomach pain
- constipation

- back pain
- pain in your hands or feet (pain in extremity)
- symptoms of flu
- feeling tired or weary (asthenia)
- infusion reaction, such as itching where the drip is given.

### **Additional side effects in children aged 5 to 11 years**

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

- feeling tired (fatigue).

### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Evkeeza**

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 carton and vial after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C to 8 °C).

Do not freeze. Do not shake.

Store in the original carton to protect from light.

Do not use this medicine if you notice it is cloudy, discoloured or contains particulate matter.

Do not store any unused portion of the infusion solution for re-use. Any unused portion of the infusion solution should not be re-used and should be disposed in accordance with local requirements.

## **6. Contents of the pack and other information**

### **What Evkeeza contains**

- The active substance is evinacumab.

Each 1 ml of concentrate for solution for infusion contains 150 mg of evinacumab.

Each vial contains either 345 mg of evinacumab in 2.3 ml of concentrate or 1 200 mg of evinacumab in 8 ml of concentrate.

- The other ingredients are proline, arginine hydrochloride, histidine hydrochloride monohydrate, polysorbate 80, histidine and water for injections.

### **What Evkeeza looks like and contents of the pack**

Evkeeza concentrate for solution for infusion is a clear to slightly opalescent, colourless to pale yellow solution.

It is available in packs containing either 1 glass vial of 2.3 ml of concentrate or 1 glass vial of 8 ml of concentrate.

**Marketing Authorisation Holder**

Ultragenyx Germany GmbH  
Rahel-Hirsch-Str. 10  
10557 Berlin  
Germany

**Manufacturer**

Ultragenyx Netherlands B. V.  
Evert van de Beekstraat 1, Unit 104  
1118 CL Schiphol  
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ultragenyx Germany GmbH, DE  
Tel: + 49 30 20179810

**This leaflet was last revised in November 2024.**

Evkeeza has been authorised under ‘exceptional circumstances’. This means that due to the rarity of the disease it has been impossible to get complete information on this medicine. Any new information on Evkeeza will be reviewed 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>

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The following information is intended for healthcare professionals only:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Instructions for use

*Preparation of solution*

Evkeeza is supplied as a single use vial only. During preparation and reconstitution a strictly aseptic technique should be used.

- Visually inspect the medicinal product for cloudiness, discolouration or particulate matter prior to administration.
- Discard the vial if the solution is cloudy or discoloured or contains particulate matter.
- Do not shake the vial.
- Withdraw the required volume of evinacumab from the vial(s) based on patient’s body weight and transfer into an intravenous infusion bag containing sodium chloride 9 mg/ml (0.9%) or dextrose 50 mg/ml (5%) for infusion. Mix the diluted solution by gentle inversion.
- The final concentration of the diluted solution should be between 0.5 mg/ml to 20 mg/ml.
- Do not freeze or shake the solution.

- Discard any unused portion left in the vial.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

#### *After dilution*

Once prepared, administer the diluted solution immediately. If the diluted solution is not administered immediately, it may be stored temporarily either:

- under refrigeration at 2 °C to 8 °C for no more than 24 hours from the time of infusion preparation to the end of the infusion
- or
- at room temperature up to 25 °C for no more than 6 hours from the time of infusion preparation to the end of the infusion.

#### *Administration*

- If refrigerated, allow the solution to come to room temperature (up to 25 °C) prior to administration.
- Evinacumab should be administered over 60 minutes by intravenous infusion through an intravenous line containing a sterile, in-line or add-on 0.2-micron to 5-micron filter. Do not administer evinacumab as an intravenous push or bolus.
- Do not mix other medicinal products with evinacumab or administer concomitantly via the same infusion line.

The rate of infusion may be slowed, interrupted or discontinued if the patient develops any signs of adverse reactions, including infusion-associated symptoms.