

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 12 years 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 12 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

Evkeeza is not likely to affect you being able to drive, use any tools or machines.

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 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
- infusion reaction, such as itching where the drip is given.

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

Ultragenyx UK
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This leaflet was last revised in 07/2022.

This medicine has been authorised under ‘exceptional circumstances’. This means that due to the rarity of the disease it has not been possible to obtain complete information on this medicinal product. The European Medicines Agency will review any new information which may become available every year and this SmPC will be updated as necessary.

Other sources of information

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

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 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 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.