

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **EVKEEZA**[®]

Evinacumab for Injection Concentrate for Solution for Infusion

Read this carefully before you start taking Evkeeza and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Evkeeza.

What is Evkeeza used for?

Evkeeza is used to treat adults and children aged 5 years and older with very high cholesterol caused by a condition called homozygous familial hypercholesterolaemia (HoFH). 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 cholesterol levels. When evinacumab blocks the effects of ANGPTL3, the level of LDL-cholesterol in the blood is reduced and problems caused by high LDL-cholesterol levels may also be reduced.

What are the ingredients in Evkeeza?

Medicinal ingredients: evinacumab

Non-medicinal ingredients: L-arginine hydrochloride, L-histidine, L-histidine monohydrochloride monohydrate, L-proline, polysorbate 80, and Water for Injection, USP

Evkeeza comes in the following dosage forms:

Concentrate for solution for infusion: 345 mg/2.3 mL (150 mg/mL) and 1,200 mg/8 mL (150 mg/mL). Evkeeza is supplied as one single-use vial per carton.

Do not use Evkeeza if:

- You are allergic to evinacumab or to any of the ingredients in this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Evkeeza. Talk about any health conditions or problems you may have, including:

- Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis. Symptoms may include swelling of the lips, tongue, or throat that make it difficult to swallow or breathe, and may also include wheezing, feeling dizzy, or fainting. If you notice any of these symptoms, tell your healthcare professional right away.
- If you are pregnant, think you might be pregnant, or plan to become pregnant, ask your healthcare professional for advice before taking Evkeeza. Evkeeza may harm your unborn baby. Tell your healthcare professional if you become pregnant while using Evkeeza. **For people who are able to become pregnant:**
 - Your healthcare professional may do a pregnancy test before you start treatment with Evkeeza.
 - You should use an effective method of birth control during treatment and for at least 5 months after the last dose of Evkeeza. Talk to your healthcare professional about birth control methods that you can use during this time.
- If you are breastfeeding or plan to breastfeed, ask your healthcare professional for advice before you are given Evkeeza. It is not known if Evkeeza passes into your breast milk. You and your healthcare professional should decide if you will receive Evkeeza or breastfeed.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

- Studies to test how Evkeeza interacts with other drugs have not been done.

How to take Evkeeza:

- Evkeeza will be given to you by a healthcare professional.
- Your healthcare professional will withdraw the required amount of Evkeeza from the vial and transfer it into an IV infusion bag. The IV bag contains either a salt solution equivalent to 9 mg/mL (0.9%), or sugar solution equivalent to 50 mg/mL (5%) for infusion. Diluted solution is then mixed by gentle inversion.
- The final concentration of the diluted solution should be between 0.5 mg/mL and 20 mg/mL.

Usual dose

- The usual dose for Evkeeza is 15 mg/kg administered at room temperature by intravenous (IV) infusion over 60 minutes every 4 weeks.
- If you miss any infusion appointments, call your healthcare professional as soon as possible to reschedule.
- Your healthcare professional may slow down your infusion rate, temporarily stop, or permanently stop treatment with Evkeeza if you have certain side effects.

- Your healthcare professional may prescribe other cholesterol-lowering medicines to use with Evkeeza. Use the other prescribed medicines exactly as your healthcare professional tells you to.

Overdose:

It is unlikely that you will receive too much Evkeeza as you will be closely monitored by healthcare professionals during your infusion. However, if you think you, or a person you are caring for, have taken too much Evkeeza, contact your healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of Evkeeza, call your healthcare professional as soon as possible to reschedule.

What are the possible side effects from using Evkeeza?

These are not all the possible side effects you may have when taking Evkeeza. If you experience any side effects not listed here, tell your healthcare professional.

- Abdominal pain
- Back pain
- Constipation
- Decreased energy
- Dizziness
- Flu symptoms
- Itchiness at the site of the injection
- Nausea
- Pain in legs or arms
- Runny nose
- Fatigue (for patients aged 5-11 years old)
- Sore throat or sinus infection

Serious side effects and what to do about them			
Symptom / Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
<ul style="list-style-type: none"> • Anaphylaxis (symptoms may include swelling of the lips, tongue, or throat that make it difficult to swallow or breathe, and may also include wheezing, feeling dizzy, or fainting) 			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects:

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

The storage details are as follows:

Unopened Vial

- Store the Evkeeza vial in a refrigerator (2°C to 8°C).
- Store in the original carton to protect from light.
- Do not freeze.
- Do not shake.

After opening

Once opened, Evkeeza should be diluted and used immediately.

After dilution

If the diluted solution is not used immediately, it may be stored:

- in the refrigerator 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

Keep out of reach and sight of children.

If you want more information about Evkeeza:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (<https://www.ultragenyx.com>), or by calling 1-833-388-5872.

This leaflet was prepared by Ultragenyx Pharmaceutical Inc.

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