Patient Information

EVKEEZA® (ev-kee'-zah)
(evinacumab-dgnb)
injection, for intravenous use

What is EVKEEZA?
EVKEEZA is an injectable prescription medicine used along with other low-density lipoprotein (LDL) lowering medicines in people 5 years of age and older with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH).
It is not known if EVKEEZA is safe and effective in people with other causes of high cholesterol.
The effect of EVKEEZA on heart problems such as heart attacks, stroke, or death is not known.
It is not known if EVKEEZA is safe and effective in children with HoFH under 5 years of age.

Who should not use EVKEEZA?
Do not use EVKEEZA if you are allergic to evinacumab-dgnb or to any of the ingredients in EVKEEZA. See the end of this leaflet for a complete list of ingredients in EVKEEZA.

Before receiving EVKEEZA, tell your healthcare provider about all of your medical conditions, including if you:
- are pregnant or plan to become pregnant. EVKEEZA may harm your unborn baby. Tell your healthcare provider if you become pregnant while using EVKEEZA. **People who are able to become pregnant:**
  - Your healthcare provider 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 with your healthcare provider about birth control methods that you can use during this time.
- are breastfeeding or plan to breastfeed. It is not known if EVKEEZA passes into your breast milk. You and your healthcare provider should decide if you will receive EVKEEZA or breastfeed.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive EVKEEZA?
- Your healthcare provider will give you EVKEEZA into your veins through an intravenous (IV) line over 60 minutes.
- EVKEEZA should be given every month (4 weeks).
- If you miss any infusion appointments, call your healthcare provider as soon as possible to reschedule.
- Your healthcare provider may slow down your infusion rate, temporarily stop, or permanently stop treatment with EVKEEZA if you have certain side effects. See "What are the possible side effects of EVKEEZA?"
- Your healthcare provider may prescribe other cholesterol-lowering medicines, to use with EVKEEZA. Use the other prescribed medicines exactly as your healthcare provider tells you to.

What are the possible side effects of EVKEEZA?
EVKEEZA can cause serious side effects, including:
- **Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis.** Tell your healthcare provider right away if you get any of the following symptoms:
  - 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

The most common side effects of EVKEEZA include:
- symptoms of the common cold
- flu like symptoms
- feel tired or weak
- dizziness
- pain in legs or arms
- nausea
- decreased energy

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
These are not all of the possible side effects of EVKEEZA.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of EVKEEZA.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information about EVKEEZA, talk with your healthcare provider. You can ask your healthcare provider for information about EVKEEZA that is written for health professionals.

What are the ingredients in EVKEEZA?
Active ingredient: evinacumab-dgnb
Inactive ingredients: L-arginine hydrochloride, L-histidine, L-histidine monohydrochloride monohydrate, L-proline, polysorbate 80, and Water for Injection, USP.

Manufactured by:
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For more information about EVKEEZA, go to www.EVKEEZA.com or call 1-833-EVKEEZA (833-385-3392)

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: March 2023

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