# Dosing and Administration Guide for EVKEEZA™

## Important instructions for aseptic intravenous (IV) infusion preparation and administration[1]

### Recommended dosage

- **The recommended dose of EVKEEZA is a 15 mg/kg dose** administered by IV infusion over 60 minutes once monthly (every 4 weeks)
- **If a dose is missed, administer as soon as possible.** Thereafter, EVKEEZA should be scheduled monthly from the date of the last dose
- **Assess LDL-C when clinically appropriate.** The LDL-lowering effect of EVKEEZA may be measured as early as 2 weeks after initiation

### Preparation

1. **Calculate the dose.** Volume of EVKEEZA and the number of vials required are based on the patient's body weight **(see next page for example calculation).**
2. **Visually inspect the vial(s).** EVKEEZA is a clear to slightly opalescent, colorless to pale-yellow solution. Discard if cloudy or discolored, or if it contains particulate matter. Do not shake the vial(s).
3. **Withdraw the required volume.** Transfer EVKEEZA into an IV infusion bag containing a maximum volume of 250 mL of 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Mix by gentle inversion; do not shake. The final concentration should be between 0.5 mg/mL and 20 mg/mL.
4. **Administer immediately.** Discard any unused portion left in the vial(s).
5. **Store if not used right away.** EVKEEZA does not contain a preservative. Refrigerate at 2 °C to 8 °C (36 °F to 46 °F) for no more than 24 hours from the time of preparation OR at room temperature up to 25 °C (77 °F) for no more than 6 hours from the time of infusion preparation to the end of the infusion. Do not freeze the diluted solution.

### Administration


1. **If refrigerated,** allow the diluted solution to come to room temperature prior to administration.
2. **Administer via IV infusion over 60 minutes** through an IV line containing a sterile, in-line or add-on 0.2-micron to 5-micron filter.
3. **Do not mix other medications with EVKEEZA** or administer them concomitantly via the same infusion line.
4. **Slow, interrupt, or discontinue the rate of infusion** if the patient develops any signs of adverse reactions, including infusion or hypersensitivity reactions.
5. **Can be administered without regard to the timing of lipoprotein apheresis.**

Visit **EVKEEZAhcp.com** for full dosage & administration instructions

### INDICATION

EVKEEZA™ is an ANGPTL3 (angiopoietin-like 3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH).

**Limitations of Use:**

- The safety and effectiveness of EVKEEZA have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).
- The effects of EVKEEZA on cardiovascular morbidity and mortality have not been determined.

**Please see Important Safety Information on next page and the full Prescribing Information at EVKEEZAhcp.com.**

Evkeeza™
(evinacumab-dgnb)
Injection

## How to prepare a weight-based dose of EVKEEZA[1]

**The recommended dose of EVKEEZA is 15 mg/kg administered by IV infusion over 60 minutes once monthly (every 4 weeks).**

1. Confirm your patient's weight (kg) to calculate the appropriate dose (mg) and volume required (mL).
2. Determine the number of EVKEEZA vial(s) required.
   - EVKEEZA is available in 2 vial sizes with the same concentration (150 mg/mL)
     - 2.3 mL (345 mg) single-dose vial
     - 8 mL (1200 mg) single-dose vial


### Example calculation for the amount of EVKEEZA (mL) required if your patient weighs 100 kg

$$\frac{\text{100 kg (patient's weight)} \times \text{15 mg/kg (dose)}}{\text{150 mg/mL (concentration)}} = \text{10 mL (1500 mg) of EVKEEZA required}$$

While there is more than one vial combination available, using (1) 8 mL and (1) 2.3 mL single-dose vials would yield the least amount of wastage to draw 10 mL of EVKEEZA. It is encouraged to reduce wastage as much as possible when administering EVKEEZA.

## IMPORTANT SAFETY INFORMATION

### Contraindication

EVKEEZA is contraindicated in patients with a history of serious hypersensitivity reactions to evinacumab-dgnb or to any of the excipients in EVKEEZA. Serious hypersensitivity reactions, including anaphylaxis, have occurred.

### Warnings and Precautions

**Serious Hypersensitivity Reactions:** Serious hypersensitivity reactions have occurred with EVKEEZA. If signs or symptoms of serious allergic reactions occur, discontinue EVKEEZA infusion, treat according to the standard-of-care, and monitor until signs and symptoms resolve.

**Embryo-Fetal Toxicity:** EVKEEZA may cause fetal harm when administered to pregnant patients. Advise patients who may become pregnant of the risk to a fetus. Consider obtaining a pregnancy test prior to initiating treatment with EVKEEZA. Advise patients who may become pregnant to use effective contraception during treatment and for at least 5 months following the last dose.

### Adverse Reactions

Common adverse reactions (≥5%) were nasopharyngitis (16%), influenza-like illness (7%), dizziness (6%), rhinorrhea (5%), and nausea (5%).

### Use in Specific Populations

**Pregnancy:** EVKEEZA may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. If a patient becomes pregnant while receiving EVKEEZA, healthcare providers should report EVKEEZA exposure by calling 1-833-385-3392.

**Lactation:** There are no data on the presence of evinacumab-dgnb in human milk or animal milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EVKEEZA and any potential adverse effects on the breastfed infant from EVKEEZA or from the underlying maternal condition.

**Females and Males of Reproductive Potential:** Consider pregnancy testing in patients who may become pregnant prior to starting treatment with EVKEEZA. EVKEEZA may cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use effective contraception during treatment with EVKEEZA and for at least 5 months following the last dose of EVKEEZA.

**Pediatrics:** The safety and efficacy of EVKEEZA have not been established in pediatric patients with HoFH who are younger than 12 years old.

**Reference: 1.** EVKEEZA Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals; 2021.

REGENERON


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Evkeeza™ (evinacumab-dgnb) Injection