# PATIENT INFORMATION

**EMGALITY®** *(em-GAL-it-ē)*

*(galcanezumab-gnlm)*

injection, for subcutaneous use

## What is EMGALITY?

EMGALITY is a prescription medicine used in adults for the:

- preventive treatment of migraine.
- treatment of episodic cluster headache.

It is not known if EMGALITY is safe and effective in children.

## Who should not use EMGALITY?

Do not use EMGALITY if you are allergic to galcanezumab-gnlm or any of the ingredients in EMGALITY. See the end of this Patient Information for a complete list of ingredients in EMGALITY.

## Before you use EMGALITY, tell your healthcare provider if you:

- are pregnant or plan to become pregnant. It is not known if EMGALITY will harm your unborn baby.
  - **Pregnancy Registry:** There is a pregnancy registry for women who take EMGALITY. The purpose of this registry is to collect information about the health of you and your baby. You may enroll yourself by calling 1-833-464-4724 or by visiting [www.migrainepregnancyregistry.com](http://www.migrainepregnancyregistry.com). Or you may talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. It is not known if EMGALITY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using EMGALITY.
- **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist when you get a new medicine.

## How should I use EMGALITY?

- See the Instructions for Use that come with EMGALITY prefilled pen or prefilled syringe about how to use EMGALITY the right way.
- Use EMGALITY exactly as your healthcare provider tells you to.
- EMGALITY is given by injection under the skin (subcutaneous injection).
- Inject EMGALITY in your stomach area (abdomen), thigh, back of the upper arm, or buttocks.
- Your healthcare provider should show you or a caregiver how to prepare and inject EMGALITY the right way before you start to use it.
- EMGALITY comes in 2 different types of devices:
  - a single-dose (1 time) prefilled pen
  - a single-dose (1 time) prefilled syringe
  
  Your healthcare provider will prescribe the type that is best for you.
- If you have questions about injecting the medicine, talk to your pharmacist or healthcare provider.
- **If you are using the EMGALITY 120 mg prefilled pen or prefilled syringe for migraine:**
  - Inject EMGALITY 1 time each month.
  - For the first dose (loading dose), you will get 2 separate injections one time, right after each other. You will need 2 prefilled pens or 2 prefilled syringes for your first dose (1-time loading dose).
  - For your regular monthly dose, you will get 1 injection. You will need 1 prefilled pen or 1 prefilled syringe for your regular monthly dose.
If you miss a dose of EMGALITY, inject the missed dose as soon as possible. Then inject EMGALITY 1 month from the date of your last dose to get back on a monthly dosing schedule. If you have questions about your schedule, ask your healthcare provider.

If you are using the EMGALITY 100 mg prefilled syringe for episodic cluster headache:

- You will get 3 separate injections, right after each other, using 3 prefilled syringes for each of your doses.
- Use EMGALITY at the start of a cluster period and then every month until the end of the cluster period.

If you miss a dose of EMGALITY, inject the missed dose as soon as possible. Then, if the cluster headache period has not yet ended, inject EMGALITY 1 month after your last dose to get back on a monthly dosing schedule. If you have questions about when you should use EMGALITY, ask your healthcare provider.

What are the possible side effects of EMGALITY?

EMGALITY may cause serious side effects, including:

- **Allergic reactions.** Allergic reactions, including itching, rash, hives, and trouble breathing, can happen after receiving EMGALITY. This can happen days after using EMGALITY. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms, which may be part of an allergic reaction:
  - swelling of the face, mouth, tongue, or throat
  - trouble breathing

The most common side effects of EMGALITY include:

- injection site reactions

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 EMGALITY. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EMGALITY?

- Store EMGALITY in the refrigerator between 36°F to 46°F (2°C to 8°C).
- EMGALITY may be stored out of the refrigerator in the original carton at temperatures up to 86°F (30°C) for up to 7 days. After storing out of the refrigerator, do not place EMGALITY back in the refrigerator.
- Do not freeze EMGALITY.
- Keep EMGALITY in the carton it comes in to protect it from light until time of use.
- Do not shake EMGALITY.
- Throw away EMGALITY if any of the above conditions are not followed.

Keep EMGALITY and all medicines out of the reach of children.

General information about the safe and effective use of EMGALITY.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information. Do not use EMGALITY for a condition for which it was not prescribed. Do not give EMGALITY to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about EMGALITY that is written for health professionals.

What are the ingredients in EMGALITY?

**Active ingredient:** galcanezumab-gnlm

**Inactive ingredients:** L-histidine, L-histidine hydrochloride monohydrate, Polysorbate 80, Sodium Chloride, and Water for Injection, USP.

EMGALITY prefilled pen and prefilled syringes are not made with natural rubber latex.