

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrEMGALITY®
(pronounced em-GAL-it-ē)
galcanezumab injection

www.lilly.ca

Lilly

Read this carefully before you start taking **EMGALITY** 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 **EMGALITY**.

What is EMGALITY used for?

EMGALITY is a medicine used in adults:

- to prevent migraine in patients who have at least 4 migraine days per month
- to reduce the number of attacks throughout a cluster period in patients with episodic cluster headache

How does EMGALITY work?

EMGALITY contains the active substance galcanezumab, which belongs to a group of substances called monoclonal antibodies. Galcanezumab binds to a protein called calcitonin gene-related peptide (CGRP). Increased CGRP levels in the blood have been linked to migraine and episodic cluster headache.

What are the ingredients in EMGALITY?

Medicinal ingredients: galcanezumab

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sodium chloride, water for injection

EMGALITY comes in the following dosage forms:

- 120 mg solution for injection in a 1 mL prefilled syringe for migraine
- 120 mg solution for injection in a 1 mL prefilled pen for migraine
- 100 mg solution for injection in a 1 mL prefilled syringe for episodic cluster headache

Do not use EMGALITY if:

- **You have an allergy to galcanezumab or any of the other ingredients of this medicine** (see **What are the ingredients in EMGALITY?** above).

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

- have had an allergic reaction to EMGALITY.
- have any chronic medical disease or need to take medication regularly.

Other warnings you should know about:

- Allergic reactions with EMGALITY are usually mild to moderate (such as rash or itching). Rarely patients taking EMGALITY have experienced a serious allergic reaction and the signs

may include:

- Difficulty breathing or swallowing,
- Low blood pressure, which can cause dizziness or light-headedness,
- Swelling of the neck, face, mouth, lips, tongue or throat, which may develop rapidly,
- Severe itching of the skin with a red rash or raised bumps.

If you experience any of the signs of a serious allergic reaction, stop taking EMGALITY immediately and contact your healthcare professional immediately.

Reactions may occur within minutes but may occur up to one month after taking EMGALITY.

- Tell your healthcare professional if you are pregnant, think you are pregnant, or are planning to have a baby while receiving this medicine.
- Tell your healthcare professional if you are breastfeeding or plan to breastfeed. It is not known whether EMGALITY passes into breast milk.
- EMGALITY should not be given to patients under the age of 18 years.

How to take EMGALITY:

- **See the detailed Instructions for Use that comes with this Patient Medication Information for instructions about the right way to give yourself EMGALITY injections**
- EMGALITY is given as an injection under the skin (subcutaneous injection).
- EMGALITY comes as a single-use (1 time) prefilled syringe or pen.
- If your healthcare professional decides that you or your caregiver can give the injections of EMGALITY, you or your caregiver should receive training on the right way to inject EMGALITY. Do not try to inject EMGALITY until you have been shown the right way to give the injections by a healthcare professional.
- Your healthcare professional may help you decide where on your body to inject your dose. You can also read the “**Choose your injection site**” section of the **Instructions for Use** to help you choose which area can work best for you.
- If you have vision problems, **do not** use EMGALITY prefilled syringe or pen without help from a caregiver.

Usual dose:

For migraine: The recommended dose of EMGALITY is a first dose of 240 mg (2 injections of the 120 mg/mL strength) followed by 120 mg (1 injection of the 120 mg/mL strength) every month thereafter.

EMGALITY is not intended for the acute treatment of migraine; patients should not exceed the monthly dose prescribed by the healthcare professional.

For episodic cluster headache: The recommended dose of EMGALITY is 300 mg (3 injections of the 100 mg/mL strength) at the start of a cluster period. After 3 weeks your healthcare provider will decide if you should continue treatment. If you continue treatment, EMGALITY 300 mg should not be administered more than once every month during a cluster period.

EMGALITY is not intended for the acute treatment of individual cluster headache attacks; patients should not exceed the monthly dose prescribed by the healthcare professional.

EMGALITY **should not** be used after the end of a cluster period and during the remission time.

Overdose:

If you think you have taken too much EMGALITY, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

For migraine: If you miss a dose take your dose as soon as you can. Thereafter resume monthly dosing.

For episodic cluster headache: If you take a partial dose (only 1 or 2 of the three prefilled syringes), take the missed injection(s) as soon as you can. If your healthcare provider determines that you should continue treatment, take the next complete dose one month from the date you took the missed injection(s).

What are possible side effects from using EMGALITY?

These are not all the possible side effects you may feel when taking EMGALITY. If you experience any side effects not listed here, contact your healthcare professional.

Very Common (≥ 1 in 10):

- injection site itching, redness, or swelling
- injection site pain
- injection site bruising
- injection site hardness

Common (≥ 1 in 100 and < 1 in 10)

- constipation
- dizziness
- itching
- rash

Uncommon (≥ 1 in 1000 and < 1 in 100):

- hives

Rare (≥ 1 in 10,000 and < 1 in 1000)

- serious allergic reaction

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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:

Store EMGALITY in a refrigerator at 2°C to 8°C until time of use. Keep the syringe or pen in the carton in order to protect from light.

If needed, EMGALITY may be left out of the refrigerator at a temperature up to 30°C for up to 7 days. EMGALITY should be discarded if not used within this 7-day period.

Do not freeze or shake the syringe or pen.

Keep out of reach and sight of children.

If you want more information about EMGALITY:

- 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; the manufacturer's website www.lilly.ca, or by calling 1-888-545-5972.
- Instructions for Use can be found on www.lilly.ca

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

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You may need to read this package insert again.
Please do not throw it away until you have finished your medicine.

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