

Package leaflet: Information for the patient

Emgality® 120 mg solution for injection in pre-filled pen

galcanezumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Emgality is and what it is used for
2. What you need to know before you use Emgality
3. How to use Emgality
4. Possible side effects
5. How to store Emgality
6. Contents of the pack and other information

1. What Emgality is and what it is used for

Emgality contains galcanezumab, a medicine that stops the activity of a naturally occurring substance in the body called calcitonin gene-related peptide (CGRP). People with migraine may have increased levels of CGRP.

Emgality is used to prevent migraine in adult patients who have at least 4 migraines days per month.

Emgality can reduce the frequency of migraine headache and improve your quality of life. It starts working in about a week.

2. What you need to know before you use Emgality

Do not use Emgality:

- if you are allergic to galcanezumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before or during treatment with Emgality if:

- you have a serious cardiovascular disease. Emgality has not been studied in patients with serious cardiovascular diseases.

Look out for allergic reactions

Emgality can potentially cause serious allergic reactions. You must look out for signs of these reactions while you are using Emgality. Stop using Emgality and tell your doctor or seek medical help

immediately if you notice any signs of a serious allergic reaction. Such signs are listed under “Serious side effects” in section 4..

Children and adolescents

This medicine should not be given to children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and Emgality

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are a woman able to have children, you are advised to avoid becoming pregnant while using Emgality.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. It is preferable to avoid the use of Emgality in pregnancy as the effects of this medicine in pregnant women are not known.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you should breast feed and use Emgality.

Driving and using machines

Galcanezumab could have a minor effect on your ability to drive and use machines. Some patients have had vertigo whilst using Emgality.

Emgality contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 120 mg dose, that is to say it is essentially “sodium-free”.

3. How to use Emgality

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Emgality pre-filled pen is for single use only and contains one dose of Emgality (120 mg).

- The first time you receive Emgality your doctor or nurse will inject two pens (total 240 mg).
- After the first dose, you will use one pen (120 mg) every month.

Your doctor will decide for how long you should use Emgality.

Emgality is given by injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you can inject Emgality yourself.

It is important not to try to inject yourself until you have been trained by your doctor or nurse. A caregiver may also give you your Emgality injection after proper training.

The pen must not be shaken.

Read the “Instructions for Use” for the pen carefully before using Emgality.

If you use more Emgality than you should

If you have injected more Emgality than you should, e.g. if after the first dose of 240 mg, you have injected it twice in a single month, or if anyone else has accidentally used Emgality, contact your doctor immediately.

If you forget to use Emgality

Do not take a double dose to make up for forgotten injection

If you have forgotten to inject a dose of Emgality, inject the missed dose as soon as possible and then inject the next dose after a month from that date.

If you stop using Emgality

You should not stop using Emgality without speaking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Allergic reactions with Emgality are usually mild to moderate (such as rash or itching). Serious allergic reactions may occur rarely (may affect up to 1 in 1,000 people) 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.

Tell your doctor or get emergency medical help straight away if you notice any of those signs.

Other side effects that have been reported.

Very common side effects (may affect more than 1 in 10 people):

- Injection site pain
- Injection site reactions (e.g. red skin, itching, bruising, swelling)

Common side effects (may affect up to 1 in 10 people):

- Vertigo (a feeling of dizziness or “spinning”)
- Constipation
- Itching
- Rash

Uncommon side effects (may affect up to 1 in 100 people):

- Hives (raised itchy areas of skin)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **Ireland:** HPRA Pharmacovigilance, website: www.hpra.ie, **Malta:** ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal, **United Kingdom:** Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emgality

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and on the carton after “EXP.” The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C to 8 °C). Do not freeze.

Store in the original package in order to protect from light.

Emgality may be stored unrefrigerated for single period up to 7 days when stored at temperatures up to 30 °C. If the pen is stored at a higher temperature or for a longer period it must be discarded.

Do not use this medicine if you notice that the pen is damaged, or the medicine is cloudy or has particles in it.

Do not throw away any medicines via wastewater or household waste. Ask your doctor, nurse or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Emgality contains

The active substance is galcanezumab. Each pre-filled pen contains 120 mg of galcanezumab in 1 mL solution.

The other ingredients are: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sodium chloride and water for injections.

What Emgality looks like and contents of the pack

Emgality is a solution for injection in a clear glass syringe. Its colour may vary from colourless to slightly yellow.

The syringe is encased in a disposable, single-dose pen. Pack sizes of 1, 2 or 3 pre-filled pens.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Eli Lilly Nederland B. V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

Manufacturer:

Eli Lilly Italia S.p.A., Via Gramsci 731/733, 50019, Sesto Fiorentino (FI), Italy.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland

Eli Lilly and Company (Ireland) Limited

Tel: + 353-(0) 1 661 4377

Malta

Charles de Giorgio Ltd.

Tel: + 356 25600 500

United Kingdom

Eli Lilly and Company Limited

Tel: + 44-(0) 1256 315000

This leaflet was last revised in December 2019

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>