

Package leaflet: Information for the patient

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

(galcanezumab)

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.

This product is called Emgality 120 mg solution for injection in pre-filled pen but will be referred to as Emgality throughout the leaflet.

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. Serious allergic reactions happen mainly within 1 day after having taken Emgality, but some reactions can be delayed (happen more than 1 day to 4 weeks after having taken Emgality). Some allergic reactions can be prolonged in duration. 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 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 the 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 a 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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

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.

Manufacturer:

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

or

Lilly S.A., Avda. de la Industria, 30, 28108 Alcobendas, Madrid, Spain

Procured from within the EU and repackaged for the

PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

Emgality® 120 mg solution for injection in pre-filled pen from SK: PLGB 45763/0963

Emgality® 120 mg solution for injection in pre-filled pen from DE: PLGB 45763/0986

Emgality® 120 mg solution for injection in pre-filled pen from NO: PLGB 45763/0987

POM

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For any information about this medicine, please contact the local representative of the Product Licence Holder: Abacus Medicine Ltd. tel: +44(0)2036301244 email: MedInfo@abacusmedicine.co.uk or drugsafetyuk@abacusmedicine.co.uk

This leaflet was last revised on 22.10.2024.

**Blind or partially sighted?
Is this leaflet hard to see or read?**

**Call 02036301310 or write to
info@abacusmedicine.com
to obtain the leaflet in a
format suitable for you.**

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

(galcanezumab)

UK510963U99-A1.0

For subcutaneous use



Before using your pre-filled pen (pen):

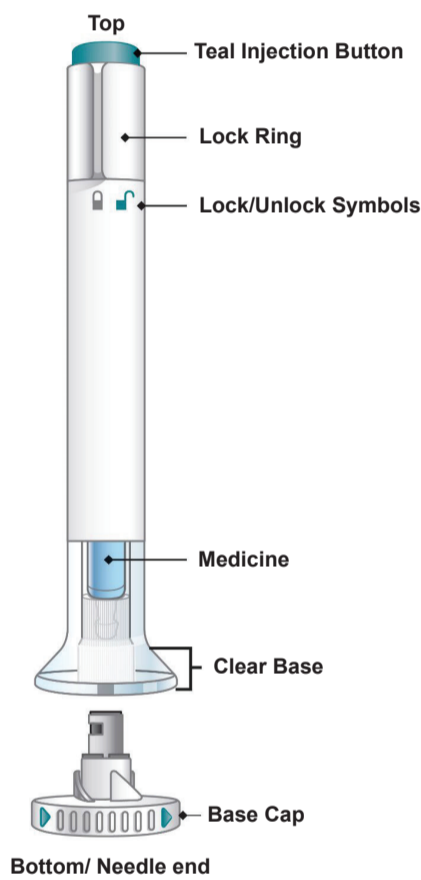
Important Information

- Your doctor or nurse should show you how to prepare and inject Emgality using the pen. Do not inject yourself or someone else until you have been shown how to inject Emgality.
- Keep these instructions and refer to them as needed.
- Each pen is for **ONE-TIME USE ONLY**. Do not share or reuse your pen. Otherwise, you may give or get an infection.
- The pen contains glass parts. Handle it carefully. If you drop it on a hard surface, do not use it. Use a new pen for your injection.
- Your doctor, pharmacist or nurse can help you decide where on your body to inject your dose. You can also read the "Choose your injection site" section of these instructions to help you choose which area can work best for you.
- If you have vision or hearing problems, **do not** use the pen without help from a caregiver.

INSTRUCTIONS FOR USE

Before you use the EMGALITY pen, read and carefully follow all the step-by-step instructions.

Parts of the Emgality pen



Before You Get Started

Take the pen from the refrigerator

Put the original package with any unused pens back in the refrigerator.

Leave the base cap on until you are ready to inject.

Do not shake.

For a more comfortable injection, leave the pen at room temperature for 30 minutes before injecting.

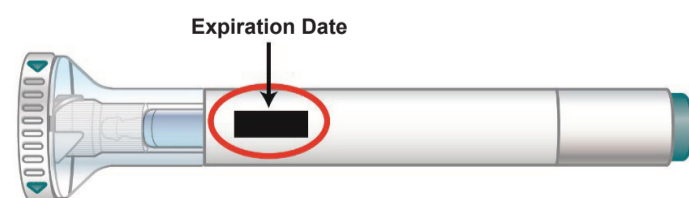
Do not microwave the pen, run hot water over it, or leave it in direct sunlight.

Inspect the pen and the medicine

Make sure you have the right medicine. The medicine inside should be clear. It may be colourless to slightly yellow.

Do not use the pen, and dispose of as directed by your doctor, pharmacist or nurse if:

- it looks damaged
- the medicine is cloudy, is discolored, or has small particles
- the expiration date printed on the label has passed
- the medicine is frozen

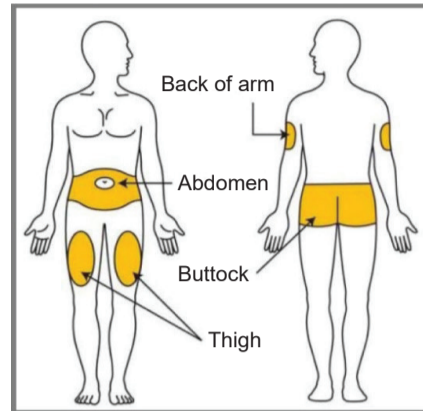


Prepare for injection

Wash your hands with soap and water before you inject Emgality. Make sure a sharps disposal container is close by.

Choose your injection site

Your doctor, pharmacist or nurse can help you choose the injection site that is best for you.

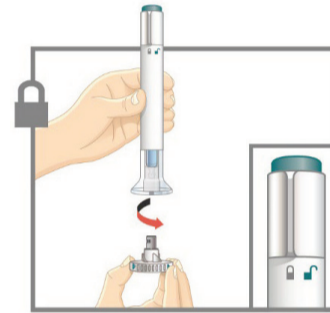


- You may inject the medicine into your stomach area (abdomen) or thigh. Do not inject within 5 centimeters of the belly button (navel).
- Another person may give you the injection in the back of your upper arm or buttock.
- Do not inject in the same spot as before. For example, if your first injection was in your abdomen, your next injection could be in another area of your abdomen.
- Clean and dry the injection site before you inject.

1 Uncap the Pen

Make sure the pen is locked. Leave the base cap on until you are ready to inject.

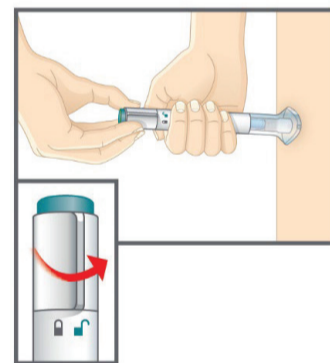
- When you are ready to inject, twist off the base cap and throw it away in the bin.
- Do not put the base cap back on – this could damage the needle.
- Do not touch the needle.



2 Place and Unlock

- Place and hold the clear base flat and firmly against your skin.

Turn the lock ring to the unlock position.

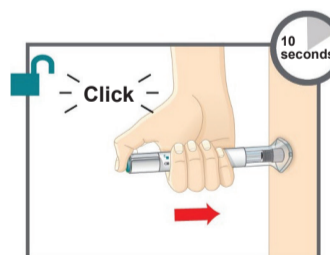


3 Press and Hold

- Press and hold the teal injection button; you will hear a loud click.

- Keep holding the clear base firmly against your skin. You will hear a second click in about 5 to 10 seconds after the first one. This second click tells you that your injection is complete.

- Remove the pen from your skin.



After You Inject Your Medicine

Dispose of the pen

DO NOT put the base cap back on. Dispose of the pen in a sharps disposal container or as directed by your doctor, pharmacist or nurse.



When you dispose of the pen and the sharps disposal container:

- Do not recycle the filled sharps container.
- Ask your doctor, pharmacist or nurse about how to dispose of medicines you no longer use.

Commonly Asked Questions

Q. What if I see air bubbles in my pen?

A. It is normal to have air bubbles in the pen. Emgality is injected under your skin (subcutaneous injection).

Q. What if there is a drop of liquid on the tip of the needle when I remove the base cap?

A. It is okay to see a drop of liquid on the tip of the needle.

Q. What if I unlocked the pen and pressed the teal injection button before I twisted off the base cap?

A. Do not remove the base cap. Dispose of the pen and get a new one.

Q. Do I need to hold the injection button down until the injection is complete?

A. This is not necessary, but it may help you keep the pen steady and firm against your skin.

Q. What if the needle did not retract after my injection?

A. Do not touch the needle or replace the base cap. Store in a safe place to avoid an accidental needlestick. Contact your doctor, pharmacist or nurse for instructions on how to return the pen.

Q. What if there is a drop of liquid or blood on my skin after my injection?

A. This is normal. Press a cotton ball or gauze over the injection site. Do not rub the injection site.

Q. What if I hear more than 2 clicks during my injection – 2 loud clicks and a soft one. Did I get my complete injection?

A. Some patients may hear a soft click right before the second loud click. That is the normal operation of the pen. Do not remove the pen from your skin until you hear the second loud click.

Q. How can I tell if my injection is complete?

A. After you press the teal injection button, you will hear 2 loud clicks. The second click tells you that your injection is complete. You will also see the grey plunger at the top of the clear base.

Read the full Package Leaflet for Emgality inside this box to learn more about your medicine.

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