

INSTRUCTIONS FOR USE

Pr**EMGALITY**[™] (em-GAL-it-ē)

galcanezumab injection

**120 mg/mL solution for subcutaneous use
prefilled pen**



www.lilly.ca

Lilly

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

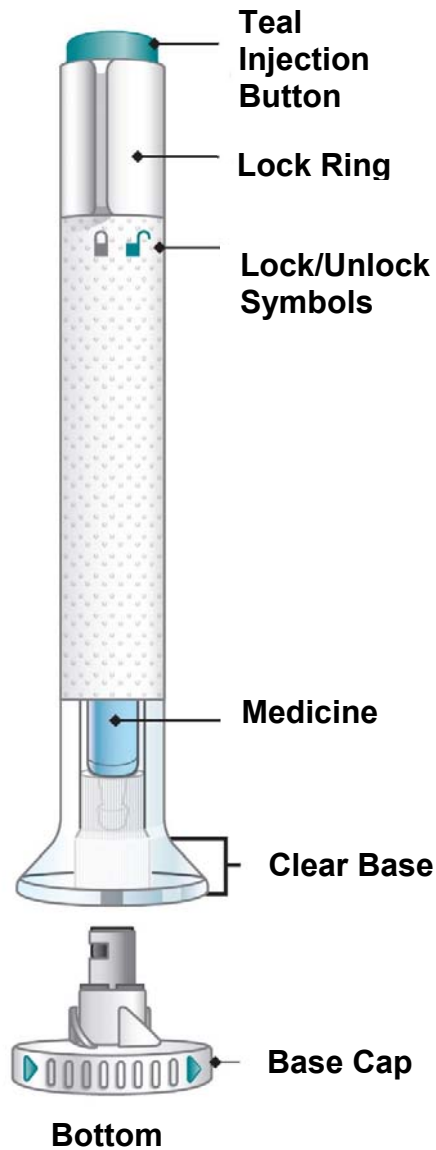
Important Information

- Your healthcare professional 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 for Use and refer to them as needed.
- Each EMGALITY Pen is for **one-time use only**. Do not share or reuse your EMGALITY Pen. 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 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 these instructions to help you choose which area can work best for you.
- If you have vision or hearing problems, **do not** use EMGALITY 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.

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.

Do not shake.

Inspect the Pen and the medicine

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

Do not use the Pen, and dispose of as directed by your healthcare professional or pharmacist 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

Expiration Date



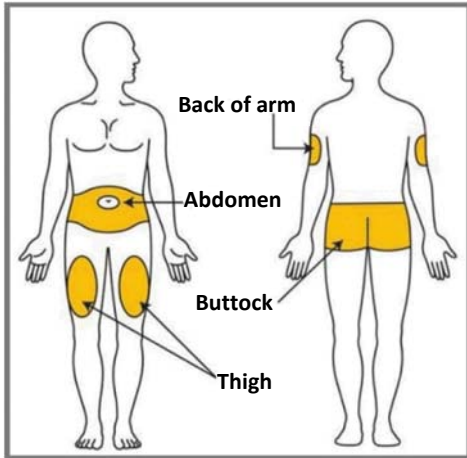
Prepare for injection

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

Choose your injection site


Your healthcare professional can help you choose the injection site that is best for you.

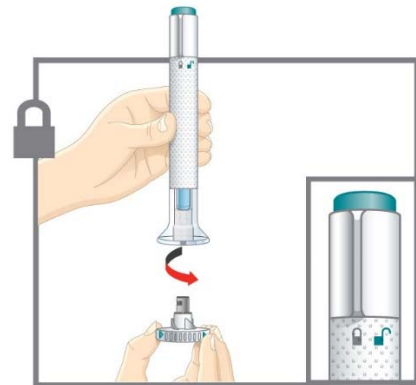
- **You** may inject the medicine into your stomach area (abdomen) or thigh. Do not inject within 2 inches of the belly button (navel).
- **Another person** may give you the injection in the back of your upper arm or buttocks.




- **Do not** inject in the exact same spot. 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.**

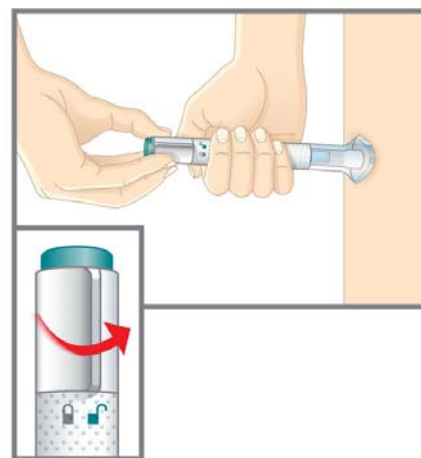
1 Uncap the Pen

-  **Make sure the Pen is locked. Leave the base cap on until you are ready to inject.**
 - Twist off the base cap and throw it away in your household trash.
 - **Do not** put the base cap back on – this could damage the needle.
 - **Do not** touch the needle.



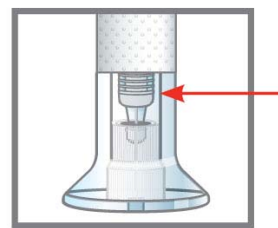
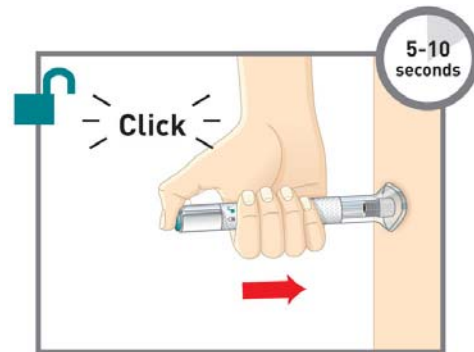
2 Place and Unlock

- Place and hold the clear base flat and firmly against your skin.
-  Turn the lock ring to the **unlock** position.



3 Press and Hold for 10 Seconds


- 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 10 seconds after the first one. This second click tells you that your injection is complete.
- Remove the Pen from your skin.



You will know your injection is complete when the grey plunger is visible.

After You Inject Your Medicine

Throw away the used Pen

- Put the used EMGALITY Pen in a sharps disposal container right away after use. **Do not** throw away (dispose of) the EMGALITY Pen in your household trash.
- 
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be provincial or local laws about how you should throw away needles and pens. For more information about the proper way to dispose of the container contact your healthcare professional.
- **Do not** recycle your used sharps disposal container.

Commonly Asked Questions

Q. What if I see bubbles in the 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 and contact 1-888-545-5972 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 heard 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.

If you have more questions about how to use the EMGALITY prefilled pen:

- Call your healthcare professional
- Call 1-888-LillyRx (1-888-545-5972)
- Visit www.lilly.ca

Storage and Handling

- Store your prefilled pen in the refrigerator between 2°C to 8°C.
- Your prefilled pen may be stored unrefrigerated for up to 7 days. Do not store above 30°C.
- Do not freeze your prefilled pen.
- Protect your prefilled pen from light until use.
- Do not shake your prefilled pen.
- Discard your prefilled pen if any of the above conditions are not followed.
- **Keep your prefilled pen and all medicines out of the reach of children.**

The Pen meets the current dose accuracy and functional requirements of ISO 11608-1 and 11608-5.

Read the Patient Medication Information for EMGALITY inside this box to learn more about your medicine.

Eli Lilly and Canada Inc., Toronto, Ontario, M1N 2E8

EMGALITY is a trademark owned or licensed to Eli Lilly and Company, its subsidiaries or affiliates.

Copyright © 2019, Eli Lilly and Company. All rights reserved.

Document revision date: July 30, 2019

EMG-120MG-PEN-0001-CA-IFU-201900730