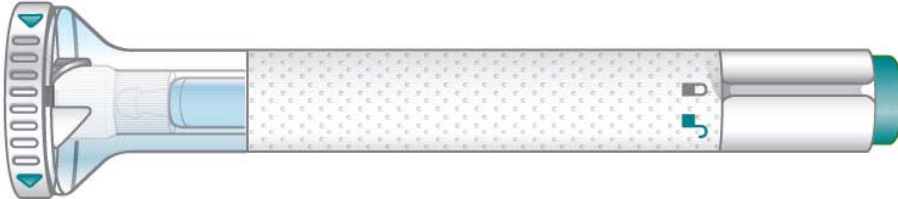


INSTRUCTIONS FOR USE

EMGALITY™ (em-GAL-it-ē)

(galcanezumab-gnlm)

injection, for subcutaneous use
Prefilled Pen



For subcutaneous injection only.

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

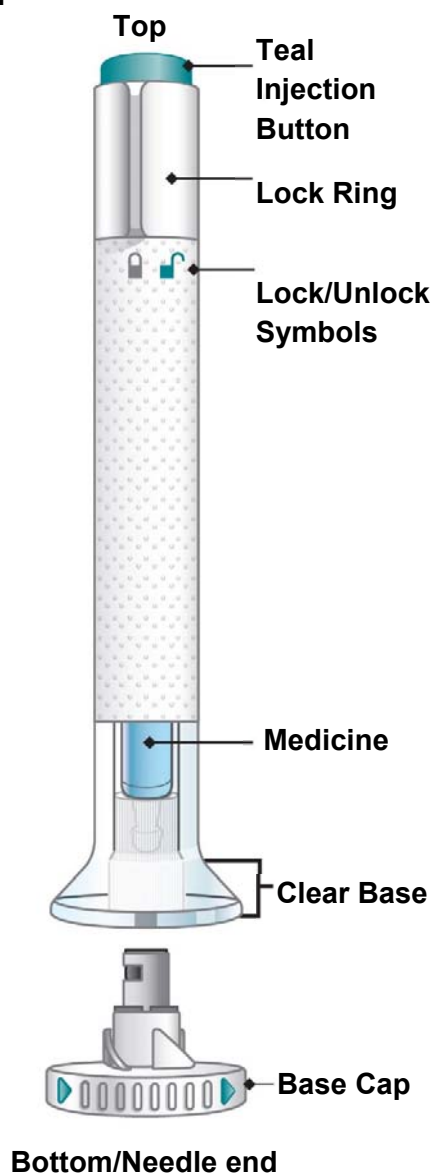
Important Information

- Your healthcare provider 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 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 provider 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.
- See “**Storage and Handling Information**” for important storage information.

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

Check your prescription.

- EMGALITY comes as a single-dose prefilled Pen.
- You will need 2 Pens for your first dose (**1-time loading dose**).
You will need 1 Pen for your monthly dose.

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

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

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.

Gather Supplies

- 1 alcohol wipe
- 1 cotton ball or piece of gauze
- 1 sharps disposal container. See “After You Inject Your Medicine.”

Inspect the Pen and the medicine

Make sure you have the right medicine. The medicine inside should be clear. Its color may be colorless to slightly yellow to slightly brown.

Do not use the Pen, and dispose of as directed by your healthcare provider 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



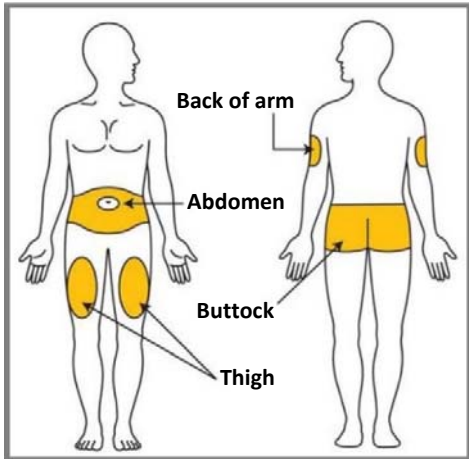
Prepare for injection

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 provider can help you choose the injection site that is best for you.

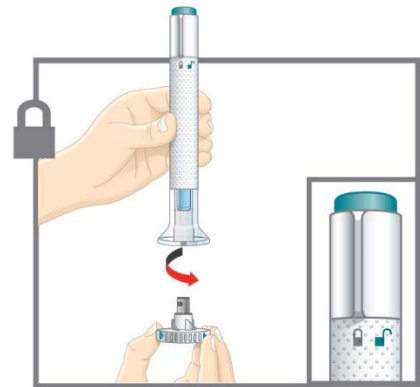
- **You** may inject the medicine into your stomach area (abdomen). Do not inject within 2 inches of the belly button (navel).
- You may inject the medicine into the front of your thighs. This area should be at least 2 inches above the knee and 2 inches below the groin.
- **Another person** may give you the injection in the back of your upper arm, or buttocks.




- **Do not** inject in the exact same spot. For example, if you are giving 2 injections for your **first dose (1-time loading dose)** and want to use the same body site for the two separate injections, choose a different injection spot. If your first injection was in your abdomen, your next injection could be in another area of your abdomen.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard.
- **Clean your injection site with an alcohol wipe. Let the injection site dry before you inject.**

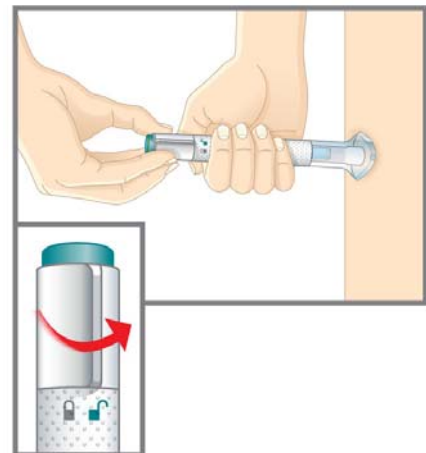
1 Uncap the Pen

-  **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.



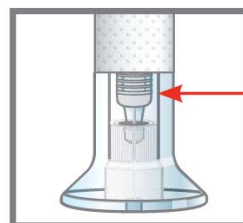
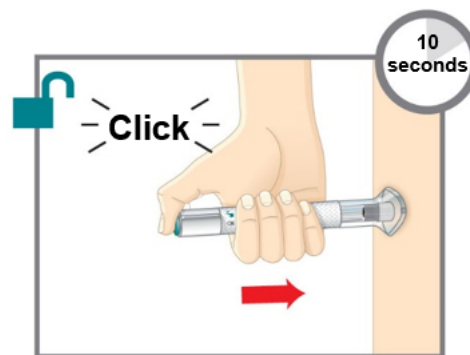
2 Place and Unlock

- 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.
- If you have bleeding at the injection site, press a cotton ball or gauze over the injection site. **Do not** rub the injection site.

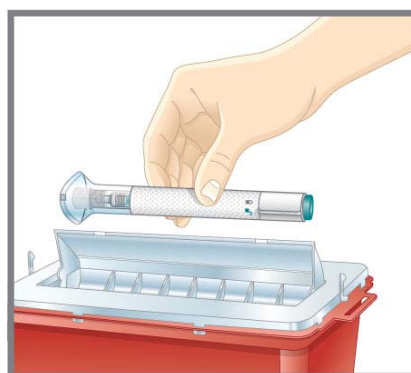


You will know your injection is complete when the gray plunger is visible.

After You Inject Your Medicine

Throw away the used Pen

- Put the used EMGALITY Pen in an FDA-cleared 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 an FDA-cleared 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 state or local laws about how you should throw away needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- **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), so these air bubbles will not harm you.

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 1-833-364-2548 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 gray plunger at the top of the clear base.

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

- Call your healthcare provider
- Call 1-833-EMGALITY (1-833-364-2548)
- Visit www.emgality.com



Storage and Handling Information

- Store your Pen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Your Pen 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** store above 86°F (30°C).
- **Do not** freeze your Pen.
- Keep your Pen in the carton it comes in to protect your Pen from light until time of use.
- **Do not** shake your Pen.

- Throw away your Pen if any of the above conditions are not followed.
- **Keep your Pen and all medicines out of the reach of children.**

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Eli Lilly and Company
Indianapolis, IN 46285, USA
US License Number 1891

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Literature Issued: September 27, 2018

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

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