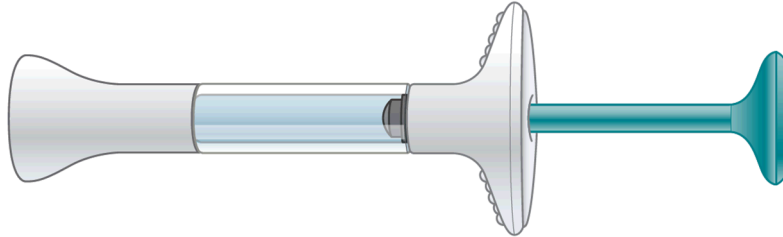


INSTRUCTIONS FOR USE

EMGALITY[®] (em-GAL-it-ē)

(galcanezumab-gnlm)

**injection, for subcutaneous use
Prefilled Syringe**



This Instructions for Use is for patients with migraine.

- If you are using EMGALITY for episodic cluster headache, there is a different Instructions for Use because the dose and number of syringes needed is different.

For subcutaneous injection only.

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

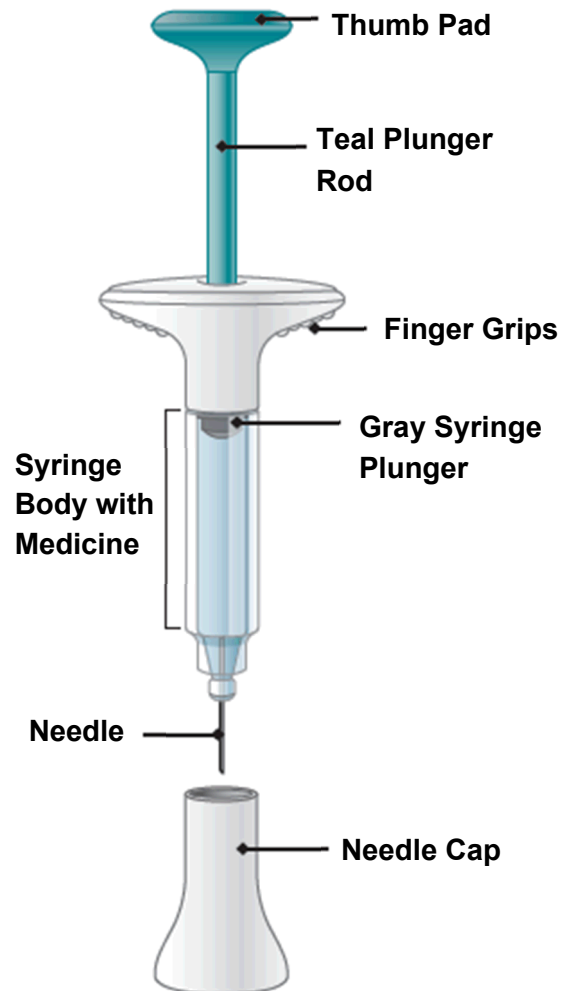
Important Information

- Your healthcare provider or nurse should show you how to prepare and inject EMGALITY using the prefilled syringe. **Do not** inject yourself or someone else until you have been shown how to inject EMGALITY.
- Keep this Instructions for Use and refer to it as needed.
- Each EMGALITY prefilled syringe is for **one-time use only**. **Do not** share or reuse your EMGALITY prefilled syringe. You may give or get an infection.
- 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 problems, **do not** use EMGALITY prefilled syringe without help from a caregiver.
- See “**Storage and Handling Information**” for important storage information.

INSTRUCTIONS FOR USE

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

Parts of the EMGALITY Prefilled Syringe



Before You Get Started

Take the Prefilled Syringe from the refrigerator

Check your prescription.

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

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

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

Leave the prefilled syringe at room temperature for 30 minutes before injecting.

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

Do not shake.

Gather Supplies

For each injection you will need:

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

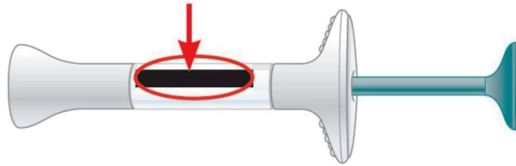
Inspect the Prefilled Syringe and the medicine

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 prefilled syringe, and throw away (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 (Exp.) printed on the label has passed
- the medicine is frozen

Expiration Date

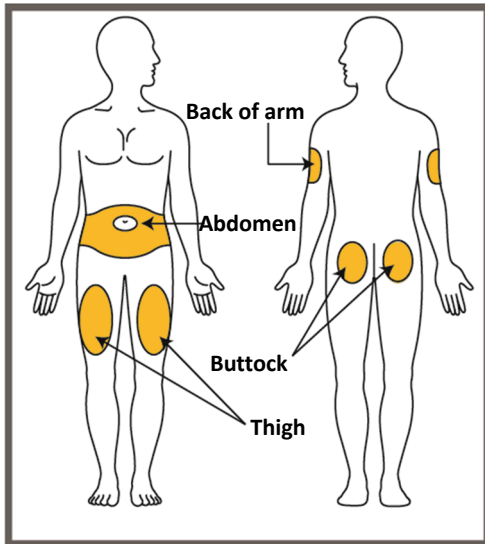


Prepare for injection

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

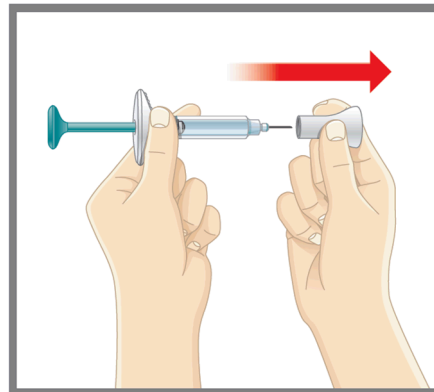
Your healthcare provider can help you choose the injection site that is best for you.



- **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.**

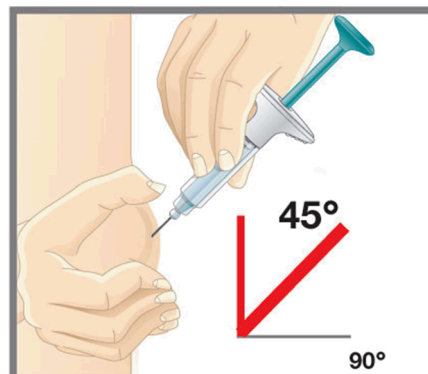
1 Uncap

- **Leave the needle cap on until you are ready to inject.**
- Pull the needle cap off and throw it away in your household trash.
- **Do not** put the needle cap back on. You could damage the needle or stick yourself by accident.
- **Do not** touch the needle.



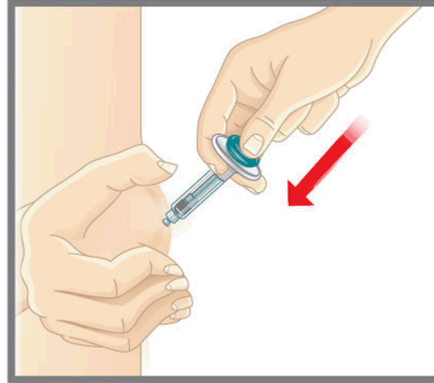
2 Insert

- Gently pinch and hold a fold of skin where you will inject.
- Insert the needle at a 45-degree angle.

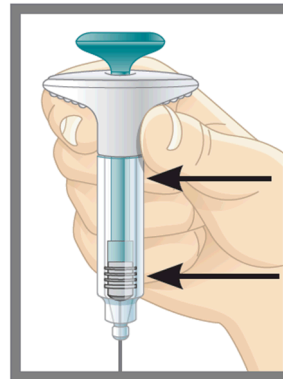


3 Inject

- Slowly push on the thumb pad to push the plunger all the way in until all the medicine is injected.
- The gray syringe plunger should be pushed all the way to the needle end of the syringe.



- You should see the teal plunger rod show through the syringe body when the injection is complete as shown.
- Remove the needle from your skin and gently let go of 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.
- **Do not** put the needle cap back on the prefilled syringe.



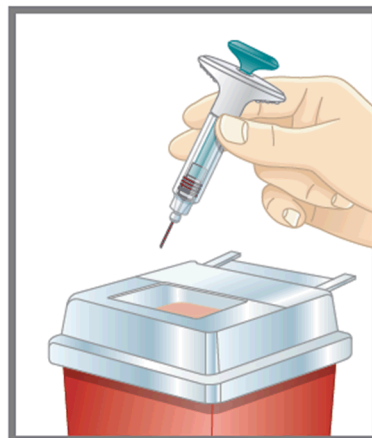
Teal plunger rod

Gray syringe plunger

After You Inject Your Medicine

Throw away the used prefilled syringe

- Put the used EMGALITY prefilled syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the EMGALITY prefilled syringe 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 air bubbles in my EMGALITY prefilled syringe?

A. It is normal to have air bubbles in the prefilled syringe. 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 needle cap?

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

Q. What if I cannot push in the plunger?

A. If the plunger is stuck or damaged:

- **Do not** continue to use the syringe
- Remove the needle from your skin
- Dispose of the syringe and get a new one

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. How can I tell if my injection is complete?

A. When your injection is complete:

- The teal plunger rod should show through the body of the syringe.
- The gray syringe plunger should be pushed all the way to the needle end of the syringe.

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

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



Storage and Handling Information

- Store your prefilled syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Your prefilled syringe 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** freeze your prefilled syringe.
- Keep your prefilled syringe in the carton it comes in to protect it from light until time of use.
- **Do not** shake your prefilled syringe.
- Throw away your prefilled syringe if any of the above conditions are not followed.
- **Keep your prefilled syringe 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.

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Indianapolis, IN 46285, USA
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