Instructions for Use
TREMFYA® (trem fye´ ah) (guselkumab)
Prefilled Syringe

Important
TREMFYA comes as a single-dose prefilled syringe containing one 100 mg dose. Each TREMFYA prefilled syringe can only be used one time. Throw the used prefilled syringe away (See Step 3) after one dose, even if there is medicine left in it. Do not reuse your TREMFYA prefilled syringe.

If your healthcare provider decides that you or a caregiver may be able to give your injections of TREMFYA at home, you should receive training on the right way to prepare and inject TREMFYA using the prefilled syringe before attempting to inject. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.

Read this Instructions for Use before using your TREMFYA prefilled syringe and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

The TREMFYA prefilled syringe is intended for injection under the skin, not into the muscle or vein. After injection, the needle will retract into the body of the device and lock into place.

Prefilled syringe parts

Before use
- Plunger
  Do not hold or pull plunger at any time.
- Safety guard
- Finger flange
- Body
  Hold syringe body below finger flange.
- Viewing window

After use
- Needle cover
  Do not remove until you are ready to inject TREMFYA (See Step 2).
- Plunger locks
- Safety guard activates
- Needle retracts into the body

Storage information

Store in refrigerator at 36° to 46°F (2° to 8°C).
Do not freeze TREMFYA prefilled syringe.

Keep TREMFYA prefilled syringe and all medicines out of reach of children.
Do not shake your TREMFYA prefilled syringe.

Keep TREMFYA prefilled syringe in the original carton to protect from light and physical damage.

You will need these supplies:
- 1 TREMFYA prefilled syringe
Not provided in the TREMFYA prefilled syringe carton:
- 1 Alcohol swab
- 1 Cotton ball or gauze pad
- 1 Adhesive bandage
- 1 Sharps container (See Step 3)
1. Prepare for your injection

Inspect carton
Remove your TREMFYA prefilled syringe carton from the refrigerator. Keep the prefilled syringe in the carton and let it sit on a flat surface at room temperature for at least 30 minutes before use.
Do not warm the prefilled syringe any other way.
Check the expiration date (‘EXP’) on the back panel of the carton.
Do not use your prefilled syringe if the expiration date has passed.
Do not inject TREMFYA if the perforations on the carton are broken. Call your healthcare provider or pharmacist for a refill.

Choose injection site
Select from the following areas for your injection:
- Front of thighs (recommended)
- Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)
- Back of upper arms (only if someone else is giving you the injection)
Do not inject into skin that is tender, bruised, red, hard, thick, scaly or affected by psoriasis.

Clean injection site
Wash your hands well with soap and warm water.
Wipe your chosen injection site with an alcohol swab and allow it to dry.
Do not touch, fan, or blow on the injection site after you have cleaned it.

Inspect liquid
Take your TREMFYA prefilled syringe out of the carton.
Check the TREMFYA prefilled syringe liquid in the viewing window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see one or more air bubbles. This is normal.
Do not inject if the liquid is cloudy or discolored, or has large particles. Call your healthcare provider or pharmacist for a refill.
2. Inject TREMFYA using prefilled syringe

Remove needle cover
Hold your prefilled syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

Inject TREMFYA within 5 minutes of removing the needle cover.
Do not put needle cover back on, as this may damage the needle or cause a needle stick injury.
Do not touch needle or let it touch any surface.
Do not use a TREMFYA prefilled syringe if it is dropped. Call your healthcare provider or pharmacist for a refill.

Position fingers and insert needle
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.
Do not touch plunger or area above finger flange as this may cause the needle safety device to activate.
Use your other hand to pinch skin at the injection site. Position syringe at about a 45 degree angle to the skin.
It is important to pinch enough skin to **inject under the skin** and not into the muscle.
Insert needle with a quick, dart-like motion.

Release pinch and reposition hand
Use your free hand to grasp the body of the prefilled syringe.

Press plunger
Place thumb from the opposite hand on the plunger and press the plunger **all the way down until it stops**.

Release pressure from plunger
The safety guard will cover the needle and lock into place, removing the needle from your skin.
3. After your injection

Dispose of your prefilled syringe
Put your used TREMFYA prefilled syringe in an FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your TREMFYA prefilled syringe in your household trash.

Do not recycle your used sharps disposal container.

For more information, see “How should I dispose of the used prefilled syringe?”

Check injection site
There may be a small amount of blood or liquid at the injection site. Hold pressure over your skin with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site.

If needed, cover injection site with a bandage.

Need help?
Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback call 800-JANSSEN (800-526-7736).

How should I dispose of the used prefilled syringe?
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
• 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 used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: www.fda.gov/safesharpsdisposal

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

Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044
US License No. 1864
INSTRUCTIONS FOR USE
TREMFYA® [trem fye’ ah] (guselkumab) injection, for subcutaneous use
One-Press Patient-Controlled Injector

This “Instructions for Use” contains information on how to inject TREMFYA.

Important Information You Need to Know Before Injecting TREMFYA
TREMFYA comes in a single-dose One-Press injector containing one 100 mg dose.

During injection, push handle all the way down until teal body is not visible to inject the full dose. DO NOT LIFT ONE-PRESS during injection. If you do, the One-Press will lock and you will not get the full dose.

Each One-Press injector can only be used one time. Throw away (See Step 3) after one dose, even if there is medicine left in it. Do not reuse your One-Press injector.

If your healthcare provider decides that you or a caregiver may be able to give your injections of TREMFYA at home, you should receive training on the right way to prepare and inject TREMFYA using the One-Press injector. Do not try to inject yourself until you have been trained by your healthcare provider.

Please read this Instructions for Use before using your One-Press injector and each time you get a new One-Press injector. There may be new information.

This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

Storage information
Store in refrigerator at 36° to 46°F (2° to 8°C). Do not freeze your One-Press injector. Do not shake your One-Press injector.

Keep your One-Press injector and all medicines out of reach of children. Keep your One-Press injector in the original carton to protect from light and physical damage.

Need help?
Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback call 800-JANSSEN (800-526-7736).
One-Press injector parts

Before use

Handle

Teal Body

Window

Needle Guard

Bottom Cap
Remove cap before injecting (see Step 2).

After use

Handle is Pressed all the way down.

The teal body is not visible.

After lifting, the needle guard locks and the yellow band is visible. **Do not** lift during the injection.

You will need:
- 1 One-Press injector

Not provided in the carton:
- 1 Alcohol swab
- 1 Cotton ball or gauze pad
- 1 Adhesive bandage
- 1 Sharps container (See Step 3)
1. Preparing to Inject TREMFYA

Inspect carton and allow TREMFYA to come to room temperature
Remove your One-Press injector carton from the refrigerator.
Keep your One-Press injector in the carton and let it sit on a flat surface at room temperature for at least 30 minutes before use.
Do not warm your One-Press injector any other way.

Check the expiration date (‘EXP’) on the carton
Do not use your One-Press injector if the expiration date has passed.
Do not inject TREMFYA if the seal on the carton is broken.
Call your healthcare provider or pharmacist for a new One-Press injector.

Choose injection site
Select from the following areas for your injection:
• Front of thighs (recommended)
• Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)
• Back of upper arms (only if someone else is giving you the injection)
Do not inject into skin that is tender, bruised, red, hard, thick, scaly, or affected by psoriasis.
1. Preparing to Inject TREMFYA (continued)

**Wash hands**
Wash your hands well with soap and warm water.

**Clean injection site**
Wipe your chosen injection site with an alcohol swab and allow it to dry.

**Do not** touch, fan, or blow on the injection site after you have cleaned it.

**Inspect liquid in window**
Take your One-Press injector out of the carton.

Check the liquid in the window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see one or more air bubbles. This is normal.

**Do not** inject if the liquid is:
- cloudy,
- discolored, or
- has large particles.

Call your healthcare provider or pharmacist for a new One-Press injector.
2. Injecting TREMFYA

**Pull off bottom cap**
Keep hands away from the needle guard after the cap is removed. It is normal to see a few drops of liquid.

**Inject TREMFYA within 5 minutes of removing the cap.**

**Do not** put the cap back on. This could damage the needle.

**Do not** use a One-Press injector if it is dropped after removing the cap. Call your healthcare provider or pharmacist for a new One-Press injector.

**Place straight on skin.**
Push handle all the way down until teal body is not visible

**DO NOT LIFT ONE-PRESS during injection!**
If you do, the needle guard will lock, showing a yellow band, and you will not get the full dose.

You may hear a click when the injection begins. Keep pushing.

**If you feel resistance, keep pushing. This is normal.**
The medication injects as you push. Do this at a speed that is comfortable for you.

**Confirm your injection is complete**
Your injection is complete when:
- The teal body is not visible.
- You cannot press the handle down anymore.
- You may hear a click.

**Lift straight up**
The yellow band indicates that the needle guard is locked.
3. After your injection

Dispose of your One-Press injector

Put your used One-Press injector in a sharps disposal container right away after use.

Do not throw away (dispose of) your One-Press injector in your household trash.

Do not recycle your used sharps disposal container.

For more information, see “Disposing of TREMFYA One-Press injector”.

Check injection site

There may be a small amount of blood or liquid at the injection site. Hold pressure over your skin with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site.

If needed, cover injection site with a bandage.

Disposing of TREMFYA One-Press injector

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
- 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 used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: www.fda.gov/safesharpsdisposal. You may also consult your pharmacist.

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

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