

TREMFYA® (guselkumab)

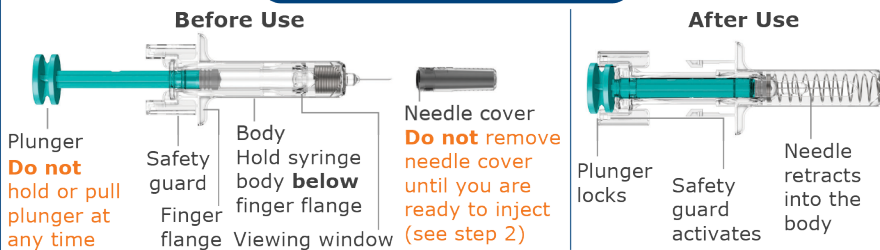
Instructions for Use - TREMFYA Prefilled Syringe

Important

TREMFYA comes as a single-use, single-dose 100 mg/mL prefilled syringe to be injected under the skin. The first self-injection by a patient or caregiver should be performed under the supervision and guidance of a qualified healthcare professional for proper training in subcutaneous injection technique. Following this training, with the approval of a healthcare provider, self-injection at home may be allowed. The TREMFYA Medication Guide and Instructions for Use should be reviewed before using the prefilled syringe and prior to each refill.

[Click here](#) to view injection demonstration video. The injection demonstration video and instruction manuals are not meant to replace the Instructions for Use (IFU) that come with your TREMFYA medication.

Prefilled Syringe Parts



Storage Information

- Store in refrigerator at **36°-46°F (2°-8°C)**
- **Do not freeze** or shake
- **Keep out of reach of children**
- **Keep in original carton to protect from light and physical damage**

Gather the Following Supplies



1 TREMFYA prefilled syringe



1 alcohol swab



1 cotton ball or gauze pad



1 adhesive bandage





1 sharps container


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Prepare


Inspect carton

- Keep prefilled syringe in carton, and let it sit on a flat surface at room temperature for **at least 30 minutes** before use
- **Do not** warm any other way 
- **Do not** use if expiration date has passed or if carton perforations are broken 

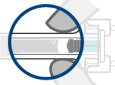
Choose injection site

- Injection sites include:
 - **Front of thighs** (recommended)
 - Lower stomach area, except for 2-inches around belly-button
 - Back of upper arms (only if someone else is injecting)
 - **Do not** inject into tender, bruised, red, hard, thick, scaly, or psoriasis affected skin
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Clean injection site

- Wash your hands with soap and warm water
- Wipe chosen injection site with alcohol swab and allow it to dry 
- **Do not** touch, fan, or blow on injection site

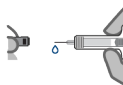
Inspect liquid through viewing window

- The liquid should be clear to slightly yellow and may have tiny white or clear particles, or air bubbles
- **Do not** inject if liquid is cloudy or discolored, or has large particles 

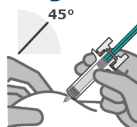
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Inject

Remove needle cover

- Hold prefilled syringe by the body and pull needle cover straight off
 - It is normal to see a drop of liquid
- **Inject within 5 minutes of removing needle cover** 
- **Do not** put needle cover back on
- **Do not** touch needle or let it touch any other surface
- If dropped, prefilled syringe should not be used

Position fingers and insert needle

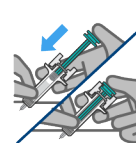
- Place thumb, index finger, and middle finger **directly under finger flange**
- **Do not** touch plunger or area above finger flange 
- Use your other hand to pinch enough skin to **inject under skin** and not into the muscle
- Insert needle with a quick, dartlike motion at about a 45° angle to the skin

Release pinch and reposition hand



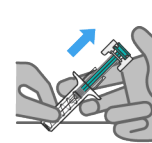
- Use your free hand to grasp the body of the prefilled syringe

Press plunger



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

Release pressure from plunger



- Safety guard will cover needle and lock into place, removing needle from your skin

Dispose of syringe

- Dispose in an FDA-cleared sharps disposal container right away
- **Do not** throw prefilled syringe in household trash or recycle the used sharps disposal container

**Check injection site**

- **Hold pressure** over injection site with a cotton ball or gauze pad until any bleeding stops
- **Do not** rub the injection site
- If needed, bandage the injection site



A small amount of blood or liquid may be seen

Disposal of 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
 - upright and stable during use
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - leak-resistant
 - properly labeled to warn of hazardous waste inside the container
- When the sharps disposal container is almost full, follow the community guidelines for the right way to dispose of the container
- There may be state or local laws about how you should throw away used needles and syringes

FOR MORE INFORMATION

Please refer to the full TREMFYA Prescribing Information, including Instructions for Use for Prefilled Syringe.

Abbreviations: C, Celsius; F, Fahrenheit; FDA, Food and Drug Administration. TREMFYA (guselkumab). [Prescribing Information]. Horsham, PA.¹

How Should You Store the TREMFYA Prefilled Syringe?

- TREMFYA is sterile and preservative-free. Discard any unused portion.¹
- Store in the refrigerator at **36° to 46°F** (2° to 8°C).¹
- **Do not** freeze the TREMFYA prefilled syringe.¹
- **Keep the TREMFYA prefilled syringe and all medicines out of reach of children.**¹
- **Do not** shake the TREMFYA prefilled syringe.¹
- **Keep the TREMFYA prefilled syringe in the original carton to protect from light and physical damage.**¹

How Should You Use TREMFYA Prefilled Syringe?

- Use TREMFYA exactly as your healthcare provider tells you to.¹
 - Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.
- You will need these supplies: 1 TREMFYA prefilled syringe, 1 alcohol swab, 1 cotton ball or gauze pad, 1 adhesive bandage, and 1 sharps disposal container.¹
- **Prepare for your injection as follows:**¹
 - **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 the 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 injection:
 - ◻ **Front of thighs** (recommended)
 - ◻ Lower stomach area, 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 liquid in the viewing window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see 1 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.
- **Inject TREMFYA using the prefilled syringe as follows:**¹
 - **Remove needle cover**
 - Hold your prefilled syringe by the body and pull the 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 the needle or let it touch any surface.
 - **Do not** use the 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 finger, and middle finger **directly under the finger flange**.
 - **Do not** touch the plunger or the area above the finger flange as this may cause the needle safety device to activate.
 - Use your other hand to pinch the skin at the injection site. Position the syringe at about a 45° angle to the skin.
 - It is important to pinch enough skin to **inject under the skin** and not into the muscle.
 - Insert the needle with a quick, dartlike motion.
 - **Release pinch and reposition hand**
 - Use your free hand to grasp the body of the prefilled syringe.
 - **Press plunger**
 - Place the thumb from the opposite hand on the plunger and press it **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.
- **After injection, follow the below steps:**¹
 - **Dispose of your prefilled syringe**
 - Put your used TREMFYA prefilled syringe in a Food and Drug Administration (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 the used sharps disposal container.
 - **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 the injection site with a bandage.

How Should You Dispose of the Used TREMFYA Prefilled Syringe?

- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:¹
 - 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 the sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of the sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.¹
- 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.

REFERENCES

1. TREMFYA (guselkumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf>.