

TREMFYA® (guselkumab)

Instructions for Use - One-Press Patient-Controlled Injector

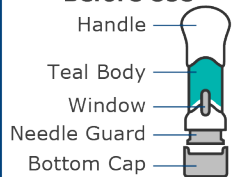
Important

TREMFYA comes as a single-use, single-dose 100 mg One-Press patient-controlled injector 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. Information provided below is in supplement to the TREMFYA Medication Guide and Instructions for Use. Review these materials before using the One-Press patient-controlled injector and each time you get a new One-Press patient-controlled injector.

[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.

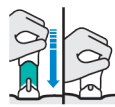
One-Press Injector

Before Use



Remove cap before injecting (see step 2)

During Use



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.

After Use

Handle is pressed all the way down

Teal body is not visible

After lifting One-Press, the needle guard locks and the yellow band is visible



Storage Information

- Store in refrigerator at **36° to 46°F** (2° to 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 One-Press injector



1 alcohol swab



1 cotton ball or gauze pad



1 adhesive bandage



1 sharps container

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Prepare

Inspect carton

- Remove the carton from the refrigerator and let it sit on a flat surface for **at least 30 minutes** at room temperature
- **Do not** warm any other way
- **Check the expiration date**
- **Do not** use the One-Press injector if the expiration date has passed
- **Do not** use the One-Press injector if the seal on the carton is broken



Choose injection site

- Injection sites include:
 - **Front of thighs** (recommended)
 - Lower stomach area, except 2 inches around belly button
 - Back of upper arms (only if someone else is injecting)
- **Do not** inject into skin that is tender, bruised, red, hard, thick, scaly, or affected by psoriasis
- **Wash your hands** with soap and warm water
- **Clean injection site** with an alcohol swab and allow it to dry
- **Do not** touch, fan, or blow on the injection site



Check liquid in window

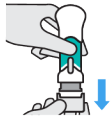


- Liquid should be clear to slightly yellow and may contain tiny white or clear particles. You may see 1 or more air bubbles, which is normal
- **Do not** inject if liquid is cloudy, discolored, or has large particles

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Inject

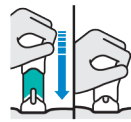
Pull off the bottom cap



- Keep hands away from needle guard after cap is removed. You may see a few drops of liquid
- **Inject within 5 minutes of removing cap**
- **Do not** put the cap back on
- **Do not** use if dropped after removing the cap

Place straight on skin. Push handle all the way down to inject

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.



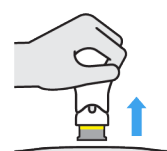
- **Push handle all the way down until teal body is not visible**
- You may hear a click when the injection begins
- **If you feel resistance, keep pushing. This is normal.**
- Medication injects as you push
- Inject at a comfortable speed

Confirm injection is complete



- Injection is complete when **the teal body is not visible**, you cannot press the handle down anymore, and you hear a click.

Lift straight up



- Yellow band shows the needle guard is locked

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After Injection

Dispose of One-Press Injector

- Dispose in a sharps disposal container right away after use
- **Do not** throw in household trash or recycle the used sharps disposal container



Check injection site

- Hold pressure over the 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



A small amount of blood or liquid may be seen

Disposal 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
 - 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 **PRESCRIBING INFORMATION** of TREMFYA for more information, including instructions for using One-Press Injector.

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

How Should You Store the TREMFYA One-Press Injector?

- Store in refrigerator at **36° to 46°F** (2° to 8°C).¹
- **Do not** freeze the TREMFYA One-Press injector.¹
- **Do not** shake the TREMFYA One-Press injector.¹
- **Keep the TREMFYA One-Press injector and all medicines out of reach of children.**¹
- **Keep the TREMFYA One-Press injector in the original carton to protect from light and physical damage.**¹

How Should You Use TREMFYA One-Press Injector?

- Use TREMFYA exactly as your healthcare provider tells you to.¹
 - Do not try to inject yourself until you have been trained by your healthcare provider.
- You will need these supplies: 1 TREMFYA One-Press injector, 1 alcohol swab, 1 cotton ball or gauze pad, 1 adhesive bandage, 1 sharps disposal container.¹
- **Prepare to inject TREMFYA One-Press Injector as follows¹:**
 - 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 the 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.
- **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 TREMFYA 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.
- **Inject TREMFYA using the One-Press injector as follows¹:**
 - **Pull off the 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.**
 - Medication injects as you push. Do this at a speed that is comfortable for you.
 - **Confirm your injection is complete**
 - 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.

- **After injection, follow the below steps¹:**
 - **Dispose of your One-Press Injector**
 - Put your used TREMFYA One-Press injector in a sharps disposal container right away after use.
 - **Do not** throw away (dispose of) your TREMFYA One-Press injector in your household trash.
 - **Do not** recycle your used sharps disposal container.
 - **Check the 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 One-Press Injector?

- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is¹:
 - 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. You may also consult your pharmacist.

REFERENCES

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