

TREMFYA® (guselkumab)

How Do I Use the One-Press Patient-Controlled Injector?

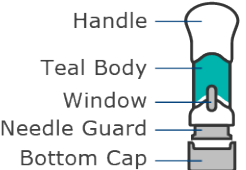
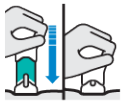

SUMMARY

Important¹

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 Injector¹

<p>Before Use</p>  <p>Remove cap before injecting (see step 2)</p>	<p>During Use</p>  <p>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.</p>	<p>After Use</p>  <p>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</p>
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Storage Information¹

- 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 it from light and physical damage**



Gather the Following Supplies¹

- | | | | | |
|--|--|--|--|--|
|  1 TREMFYA One-Press injector |  1 alcohol swab |  1 cotton ball or gauze pad |  1 adhesive bandage |  1 sharps container |
|--|--|--|--|--|

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Prepare¹


Inspect carton

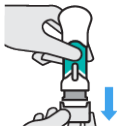
- Remove the carton from the refrigerator and let it sit on a flat surface for **at least 30 minutes** at room temperature 
- **Do not** warm any other way 
- **Check the expiration date**
- **Do not** use the One-Press injector if the expiration date has passed
- **Do not** use the One-Press injector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

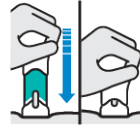
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- Liquid should be clear to slightly yellow and may contain tiny white or clear particles. You may see 1 or more air bubbles, which is normal
 - **Do not** inject if liquid is cloudy, discolored, or has large particles

2**Inject¹****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

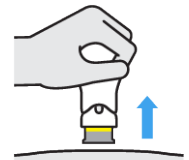
DO NOT LIFT ONE-PRESS during injection! If you do, the needle guard will lock, showing a yellow band, and you will not get the full dose.



- **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

3**After Injection¹****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 Injector¹

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

FOR MORE INFORMATION

We suggest that you review this information with your healthcare professional to address specifics regarding your healthcare treatment or for more information related to TREMFYA and instructions for using One-Press Patient-Controlled Injector.

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

ADDITIONAL INFORMATION

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare professional(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION, MEDICATION GUIDE and INSTRUCTIONS FOR USE for TREMFYA.¹

REFERENCES

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