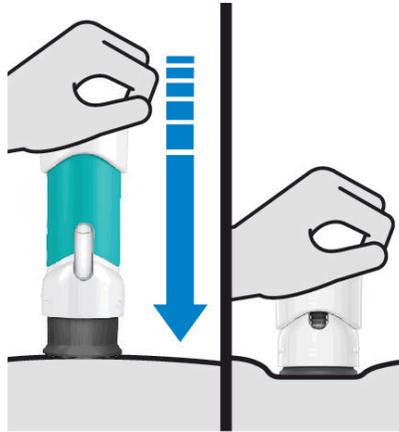


**INSTRUCTIONS FOR USE**  
**TREMFYA® [trem fye' ah]**  
**(guselkumab)**  
**injection, for subcutaneous use**  
**One-Press Patient-Controlled Injector**

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.**



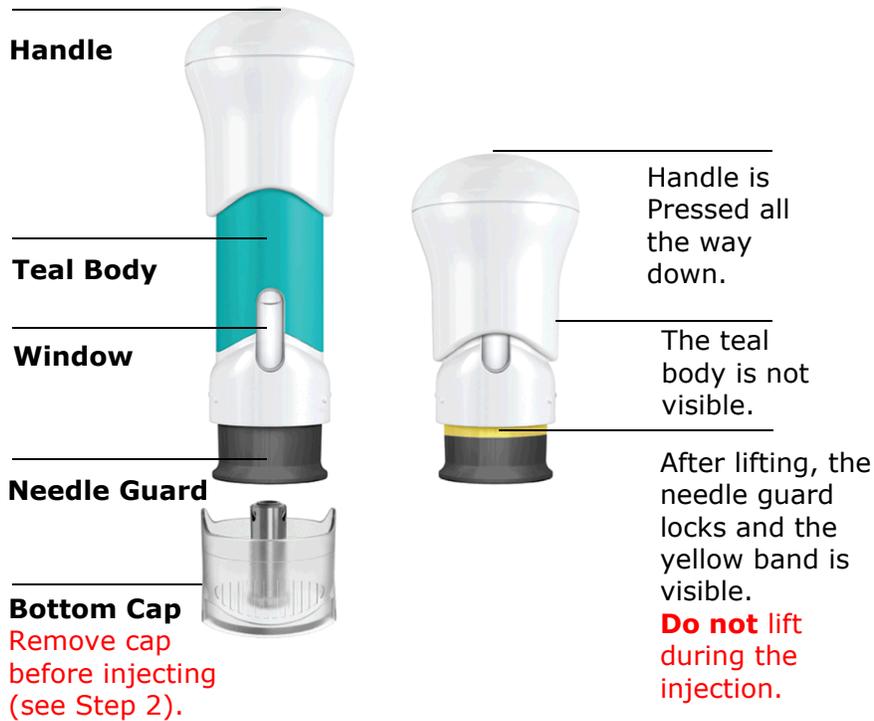
## **Need help?**

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

After use



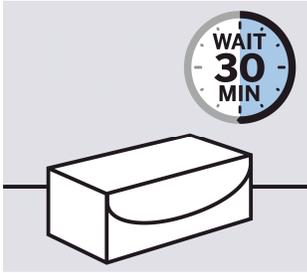
## You will need:

- 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

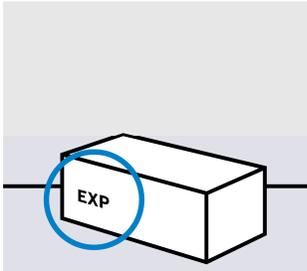


### Inspect carton and allow TREMFYA to come to room temperature

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.

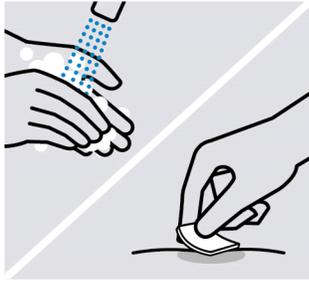


### Choose injection site

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.



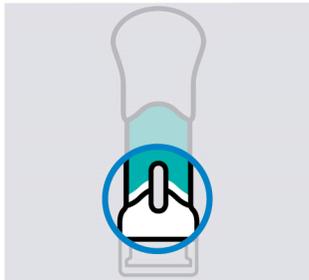
## Wash hands

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.

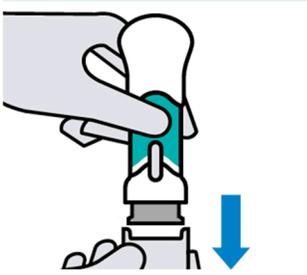
Check the liquid in the window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see one or more air bubbles. This is normal.

**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



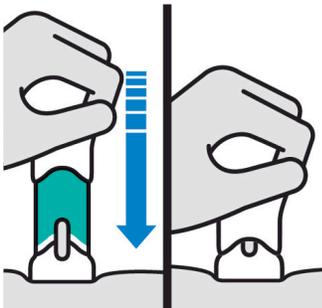
### **Pull off bottom cap**

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**

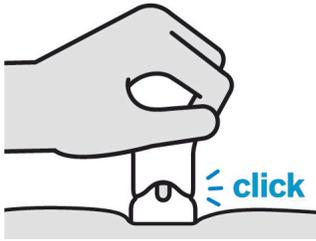
### **DO NOT LIFT ONE-PRESS during injection!**

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.**

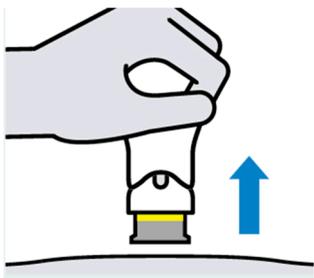
The medication injects as you push. Do this at a speed that is comfortable for you.



### **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

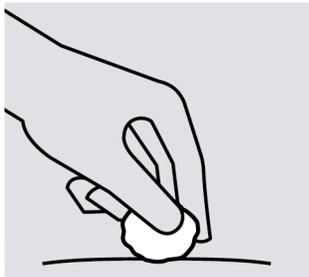


#### **Dispose of your One-Press injector**

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](http://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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Revised:

