

**Instructions for use**  
**TREMFYA®**  
(guselkumab)  
**100 mg pre-filled syringe**



**SINGLE-USE DEVICE**

**Important**

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

If your doctor 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 pre-filled syringe before attempting to inject.

Please read these Instructions for Use before using the TREMFYA pre-filled syringe and each time you get a refill. There may be new information. This instruction guide does not take the place of talking with your doctor about your medical condition or your treatment. Please also read the Package Leaflet and instructions for administration carefully before starting your injection and discuss any questions you may have with your doctor or nurse.

The TREMFYA pre-filled 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.



**Storage information**

Store in refrigerator at 2°C to 8°C. **Do not** freeze.

**Keep TREMFYA and all medicines out of reach of children.**

**Do not** shake the pre-filled syringe at any time.

**Keep TREMFYA pre-filled syringe in the original carton to protect from light and physical damage.**

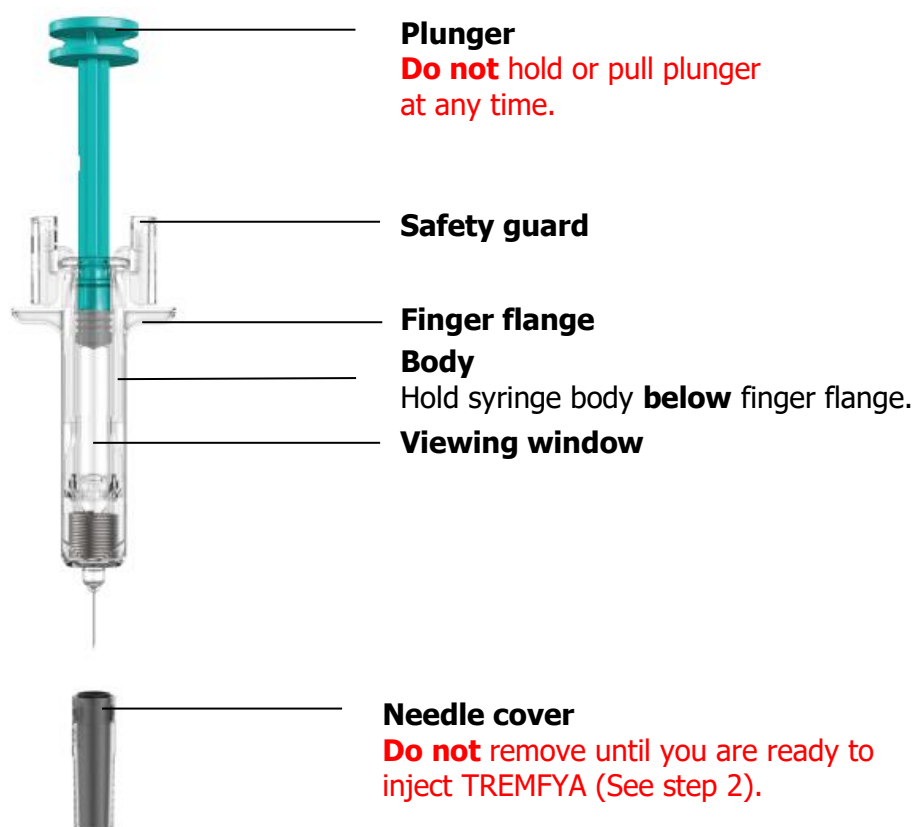


### **Need Help?**

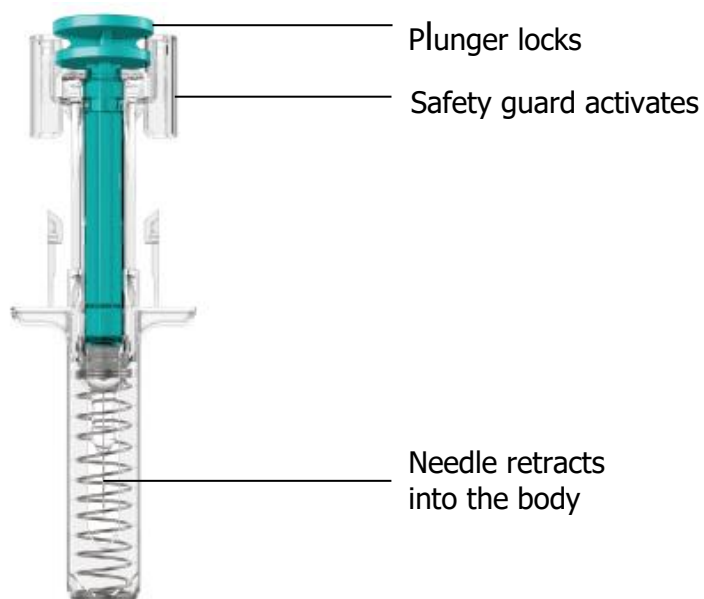
Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback refer to the Package Leaflet for your local representative contact information.

### **Pre-filled syringe at-a-glance**

Before injection



After injection



**You will need these supplies:**

- **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 carton with the pre-filled syringe from the refrigerator. Keep the pre-filled 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 any other way.

**Check the expiration date ('EXP')** on the back panel of the carton.

**Do not** use if the expiration date has passed.

**Do not** inject if the perforations on the carton are broken. Call your doctor or pharmacist for a refill.



## Choose injection site

Select from the following areas for your injection:

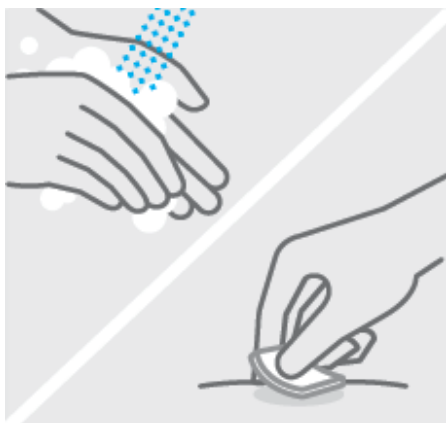
- **Front of thighs** (recommended)
- Lower abdomen

**Do not** use the 5-centimeter area around belly-button.

- Back of upper arms (if a caregiver is giving you the injection)

**Do not** inject into skin that is tender, bruised, red, scaly or hard.

**Do not** inject into areas with scars or stretch marks.

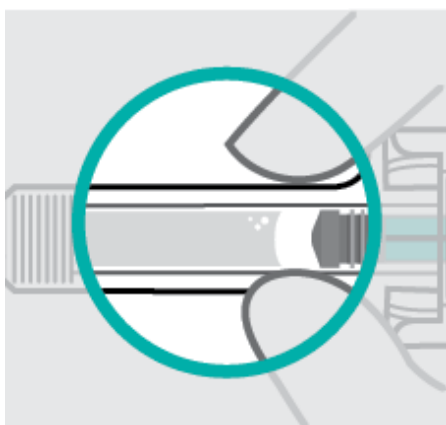


### Clean injection site

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.



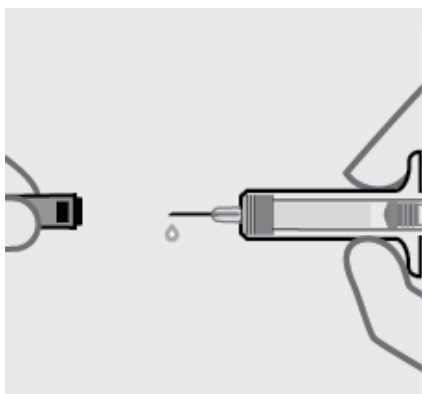
### Inspect liquid

Take the pre-filled 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 one or more air bubbles. This is normal.

**Do not** inject if the liquid is cloudy or discolored, or has large particles. If you are uncertain, call your doctor or pharmacist for a refill.

## 2. Inject TREMFYA using the pre-filled syringe



### Remove needle cover

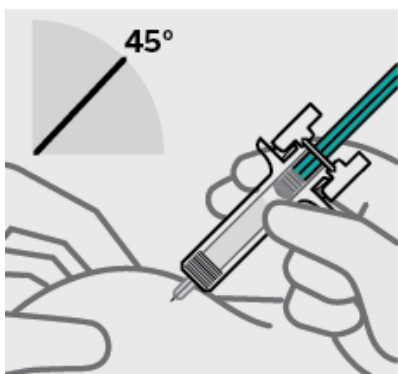
Hold syringe by the body and pull needle cover straight off.  
It is normal to see a drop of liquid.

### Inject within 5 minutes of removing the needle cover.

**Do not** put needle cover back on, as this may damage the needle.

**Do not** touch needle or let it touch any surface.

**Do not** use the TREMFYA pre-filled syringe if it is dropped. Call your doctor or pharmacist for a refill.



### Position fingers and insert needle

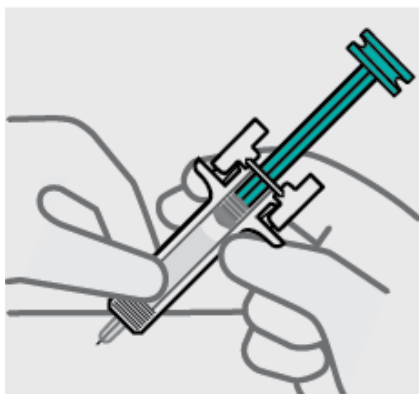
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

**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.

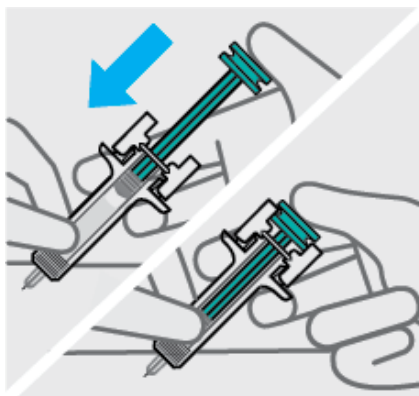
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



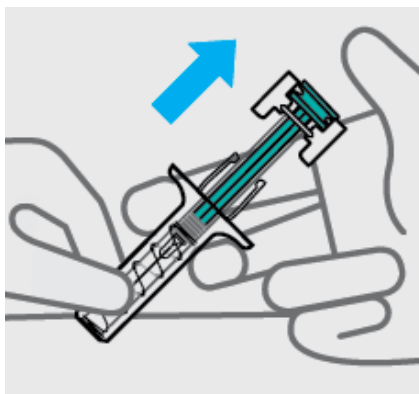
### Release pinch and reposition hand

Use your free hand to grasp the body of the 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.

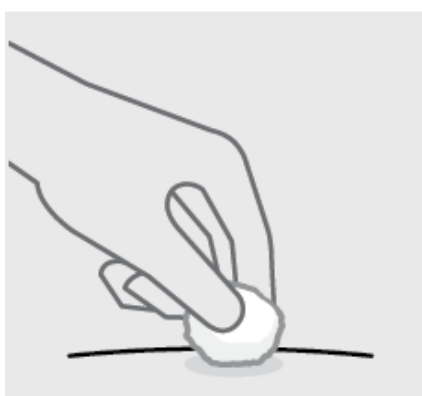
### 3. After your injection



#### Throw the used pre-filled syringe away

Put your used syringe in a sharps disposal container right away after use.

Make sure you dispose of the bin as instructed by your doctor or nurse when the container is full.



#### 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.

Your injection is now complete!

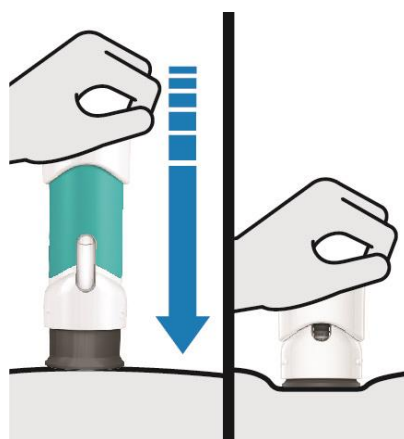
#### Instructions for use

**TREMFYA®**

(guselkumab)

**100 mg pre-filled pen (One-Press)**





**SINGLE-USE DEVICE**

### Important

If your doctor 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 pre-filled pen.

Please read these Instructions for Use before using the TREMFYA pre-filled pen and each time you get a new pre-filled pen. There may be new information. This instruction guide does not take the place of talking with your doctor about your medical condition or your treatment.

Please also read the Package Leaflet carefully before starting your injection and discuss any questions you may have with your doctor or nurse.

**During injection, push handle all the way down until teal body is not visible to inject the full dose.**

**DO NOT LIFT THE PRE-FILLED PEN during injection. If you do, the pre-filled pen will lock and you will not get the full dose.**



### Storage information

Store in refrigerator at 2° to 8°C.

**Do not** freeze.

**Do not** shake the pre-filled pen at any time.

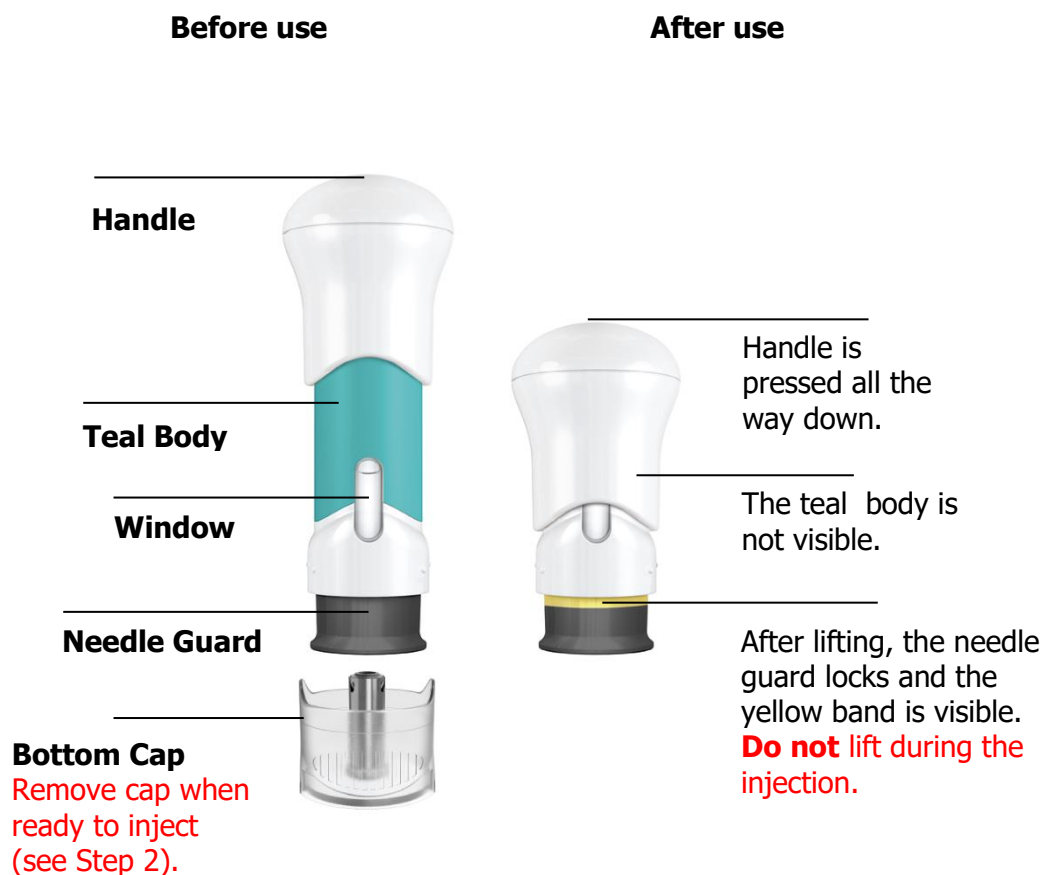
**Keep TREMFYA and all medicines out of reach of children.**



### Need help?

Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback refer to the Package Leaflet for your local representative contact information.

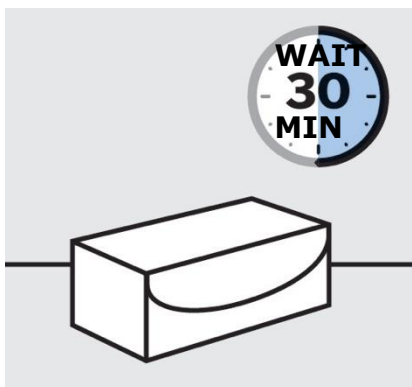
## Pre-filled pen at-a-glance



### You will need these supplies:

- **1 Alcohol swab**
- **1 Cotton ball or gauze pad**
- **1 Adhesive bandage**
- **1 Sharps container** (See step 3)

## 1. Prepare for your injection

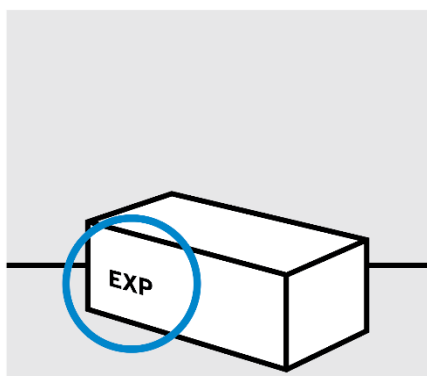


### Inspect carton and allow TREMFYA to come to room temperature

Remove carton with the pre-filled pen from the refrigerator.

Keep pre-filled pen in the carton and let it sit on a flat surface at room temperature for **approximately 30 minutes** before use.

**Do not** warm any other way.



**Check the expiration date ('EXP')** on the carton.

**Do not** use if the expiration date has passed.

**Do not** inject if the seal on the carton is broken.

Call your doctor or pharmacist for a new pre-filled pen.

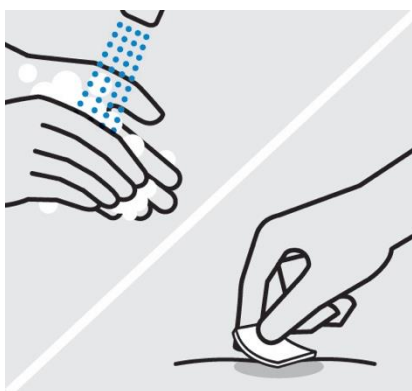


## Choose injection site

Select from the following areas for your injection:

- **Front of thighs** (recommended)
- Lower abdomen  
**Do not** use the 5-centimetre area around your belly-button.
- Back of upper arms (if a caregiver is giving you the injection)

**Do not** inject into skin that is tender, bruised, red, scaly, hard or has scars or stretch marks.



## 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 the pre-filled pen 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.

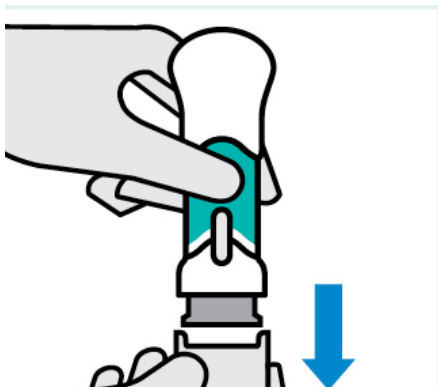
This is normal.

**Do not** inject if the liquid is:

- cloudy, or
- discolored, or
- has large particles.

If you are uncertain, call your doctor or pharmacist for a new pre-filled pen.

## 2. Inject TREMFYA using the pre-filled pen



### **Pull off bottom cap when you are ready to inject**

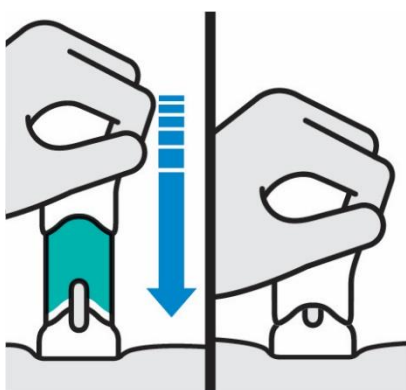
Keep hands away from the needle guard after the cap is removed. It is normal to see a few drops of liquid.

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

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

**Do not** use the pre-filled pen if it is dropped after removing the cap.

Call your doctor or pharmacist for a new pre-filled pen.



### **Place straight on skin**

### **Push handle all the way down until teal body is not visible**

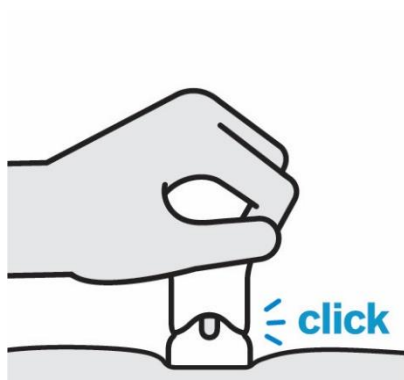
**DO NOT LIFT THE PRE-FILLED PEN DURING THE INJECTION!**

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.**

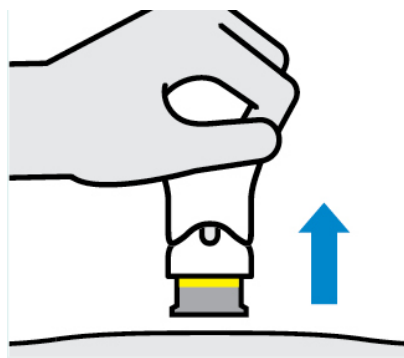
The medication injects as you push. Do this at a speed that is comfortable for you.



### Confirm injection is complete

Injection is complete when:

- **The teal body is no longer 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



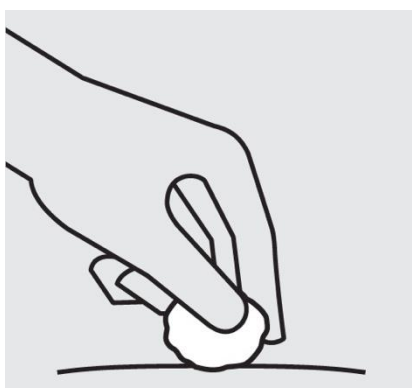
#### Throw the used pre-filled pen away

Put your used pre-filled pen in a sharps disposal container right away after use.

Make sure you dispose of the bin as instructed by your doctor or nurse when the container is full.

**Do not** throw away (dispose of) your pre-filled pen in your household waste.

**Do not** recycle your 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 injection site with a bandage.

Your injection is now complete!

MANUFACTURED BY	MARKETING AUTHORIZATION NUMBER	DATE OF AUTHORIZATION
Cilag AG, Schaffhausen, Switzerland	1C 15015/62 (NBC)	26 February 2019



**DATE OF REVISION OF THE TEXT**

100 mg Pre-filled syringe: Core IFU version 06-Nov-2024

100 mg One-press: Core IFU version 14-Aug-2024

**Imported by**

Janssen-Cilag Ltd., Bangkok, Thailand

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For any product information, please contact us at [medinfosea@its.jnj.com](mailto:medinfosea@its.jnj.com)

Please see full prescribing information at  
<https://druglink.fda.moph.go.th/U1DR1C1072621501511C>