

ข้อมูลการใช้ยาภาษาอังกฤษสำหรับผู้ป่วย

**Instructions for use
TREMFYA®**

(guselkumab)

200 mg solution for injection in pre-filled syringe.



SINGLE-USE

Important

TREMFYA comes in a single-use pre-filled syringe containing one 200 mg dose.

Your doctor will tell you if you will need to use 1 or 2 pre-filled syringes.

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.

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 read the instructions for administration carefully before starting your injection and discuss any questions you may have with your doctor or nurse.

Each TREMFYA pre-filled syringe can only be used one time. Throw the used pre-filled syringe away (see Step 4) after one dose, even if there is still medicine left in it. Do not reuse your TREMFYA pre-filled syringe.

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 device and lock into place.

**Storage information**

Store in refrigerator at 2° to 8°C

Do not freeze.

Do not shake your pre-filled syringe.

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

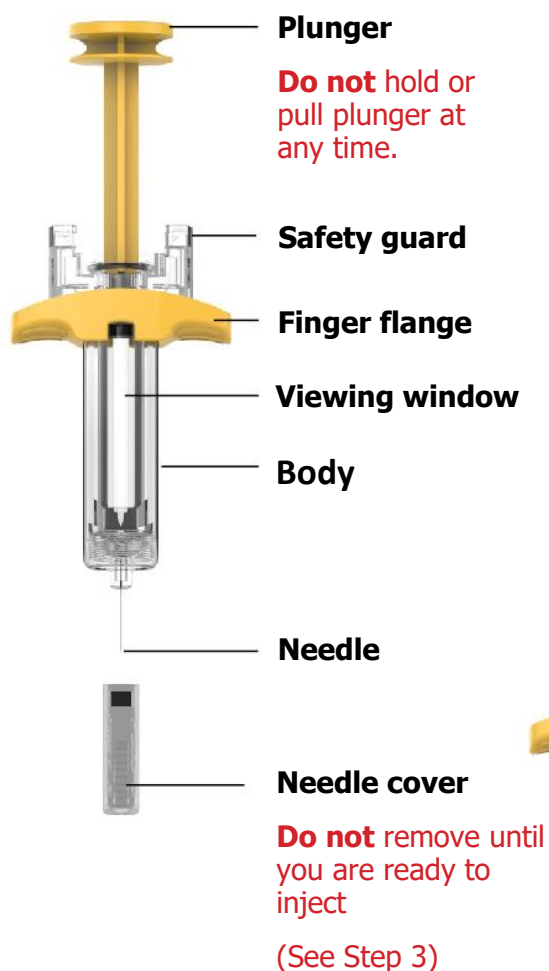
Keep TREMFYA and all medicines out of reach of children.

**Need help?**

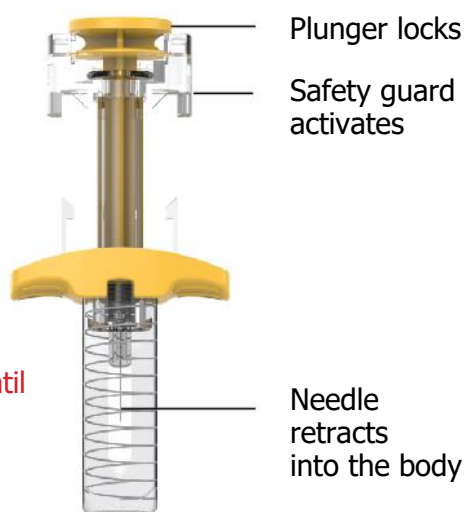
Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback contact your local representative.

Pre-filled syringe at-a-glance

Before use



After use



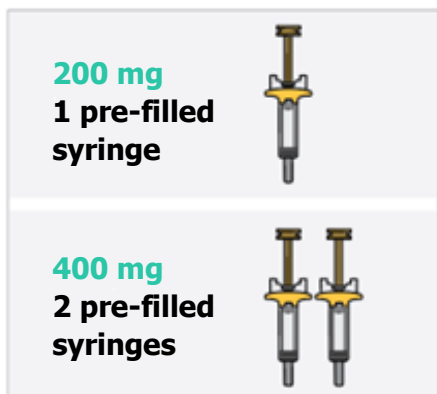
You will need:

- 1 or 2 pre-filled syringes based on the dose prescribed by your doctor

Not provided in the carton:

- Alcohol swabs
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps container (See Step 4)

1. Get ready



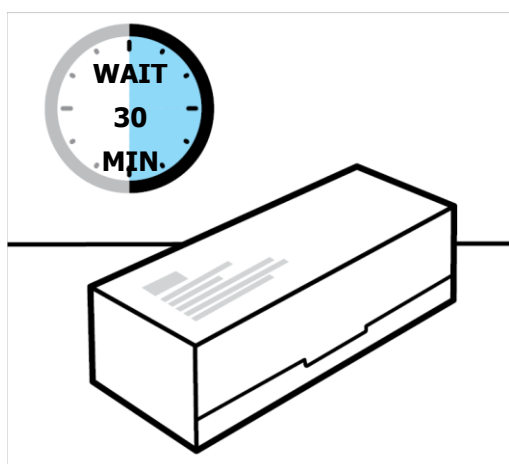
Check your dose to see if you will need to use 1 or 2 pre-filled syringes and inspect carton(s)

Remove the carton(s) with the pre-filled syringe from the refrigerator.

Check the expiration ('Expiry') date.

Do not use the pre-filled syringe if the expiration date has passed or if the seal on the carton is broken.

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

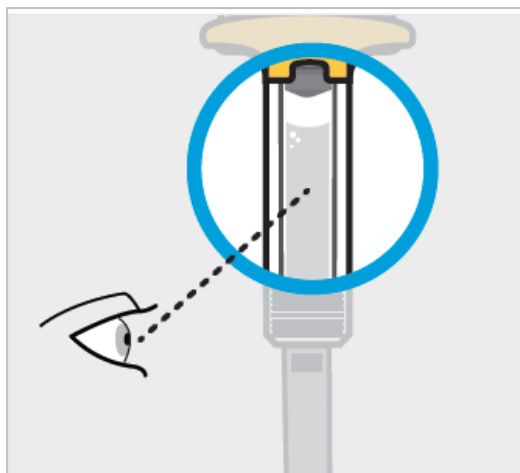


Allow TREMFYA to come to room temperature

Let the cartons sit on a flat surface at room temperature for approximately **30 minutes** before use.

Do not warm the pre-filled syringe(s) any other way.

2. Prepare for your injection



Inspect liquid to see that it is clear to slightly yellow

Take the pre-filled syringe out of the carton.

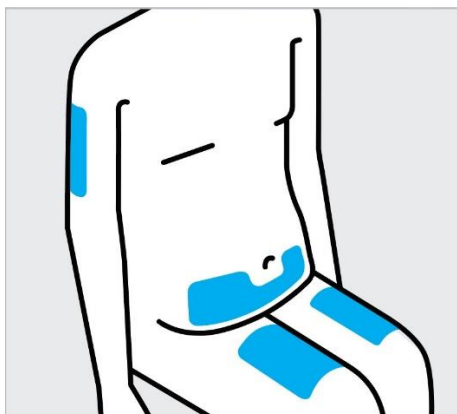
Check the liquid in the viewing window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see air bubbles. This is normal.

Do not inject if the liquid is:

- cloudy or
- discolored or
- has large particles

Do not use the pre-filled syringe if it is dropped.

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



Choose injection site

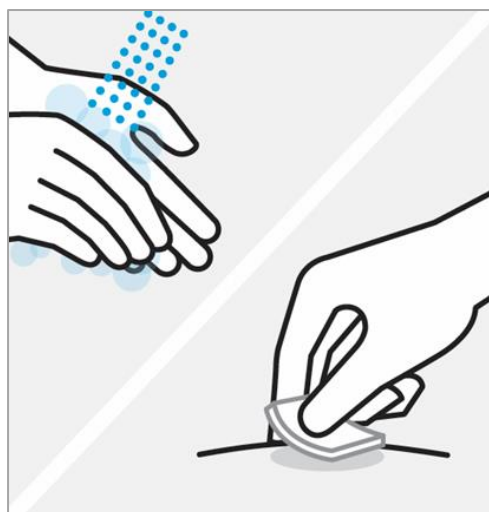
Select a site from the following areas for your injection:

- Front of thighs
- Lower stomach area (lower abdomen)
Do not use the 2-inch (5-centimeter) area around your belly-button
- Back of upper arms (if a caregiver is giving you the injection)

If you need to give 2 injections to complete your dose, choose different areas or leave at least 2 inches (5-centimeters) between injection sites.

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

Avoid areas with scars or stretch marks.



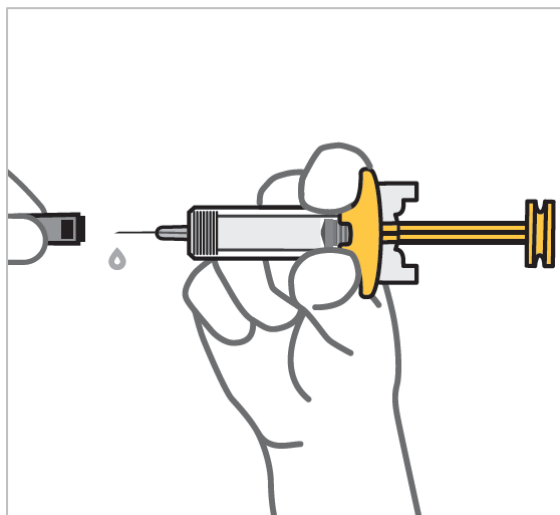
Wash hands and clean injection site

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.

3. Inject TREMFYA using the pre-filled syringe



Remove needle cover when you are ready to inject

Hold the pre-filled syringe by the body and pull needle cover straight off.

It is normal to see a few drops of liquid.

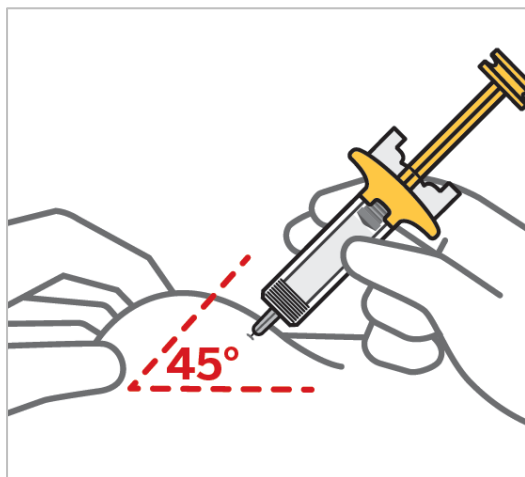
Inject TREMFYA within 5 minutes of removing the needle cover.

Do not put needle cover back on, as this may damage the needle or cause a needle stick injury.

Do not touch needle or let it touch any surface.

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

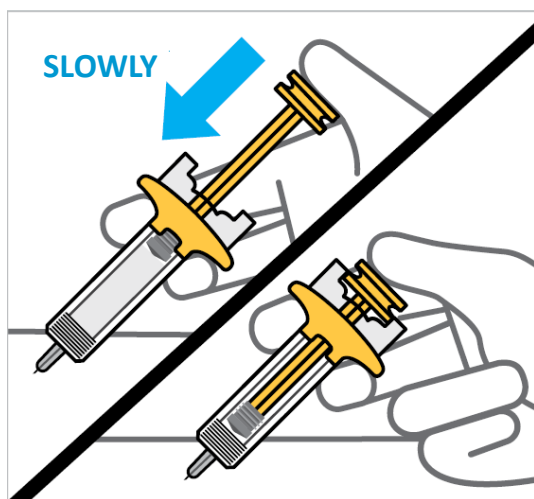
Do not hold or pull the plunger at any time.



Pinch injection site and insert needle at about a 45-degree angle

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

Insert needle with a quick dart-like motion.



Slowly press plunger all the way down until it stops to inject all of the liquid

You will feel some resistance as you press the plunger, this is normal.

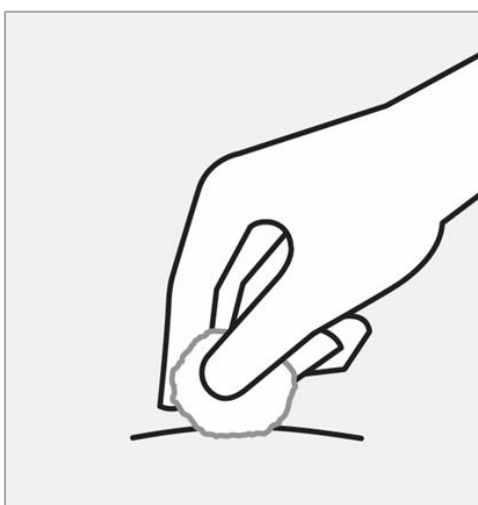


Release pressure from plunger to remove the needle from the skin

The needle will retract into the device and lock into place.

If your prescribed dose requires two injections, repeat Steps 2 to 4 with the second pre-filled syringe.

4. After your injection



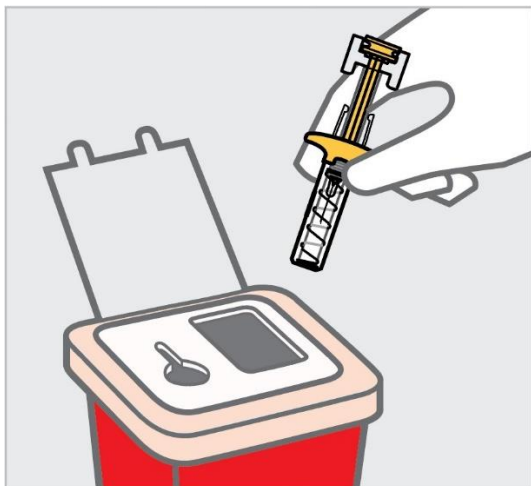
Check injection site

There may be a small amount of blood or liquid at the injection site.

Gently hold pressure over the injection site 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.

Your injection is now complete!

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

Put the used pre-filled 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.

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

Do not recycle your used sharps disposal container.

Reference: 200 mg pre-filled syringe core IFU CCDS V.16, Apr 2024

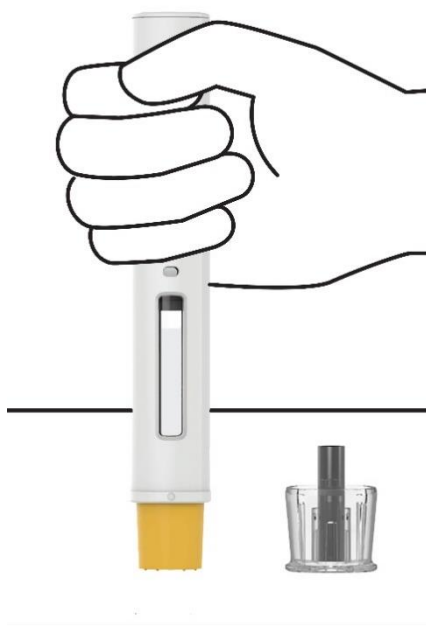
ข้อมูลการใช้ยาภาษาอังกฤษสำหรับผู้ป่วย

Instructions for use

TREMFYA®

(guselkumab)

200 mg PushPen solution for injection in pre-filled pen (autoinjector)



SINGLE-USE DEVICE

Important

TREMFYA comes in a single-use Pushpen containing one 200 mg dose.

Your doctor will tell you if you will need to use 1 or 2 Pushpens.

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 Pushpen.

Please read these Instructions for Use before using the TREMFYA Pushpen and each time you get a new Pushpen. 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 read the instructions for administration carefully before starting your injection and discuss any questions you may have with your doctor or nurse.

Each TREMFYA Pushpen can only be used one time. Throw the used Pushpen away (see Step 4) after one dose, even if there is still medicine left in it. Do not reuse your Pushpen.

**Storage information**

Store in refrigerator at 2° to 8°C.

Do not freeze.

Do not shake your Pushpen.

Keep your Pushpen in the original carton to protect from light and physical damage.

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 contact your local representative.

Pushpen at-a-glance

Before use

You will need:

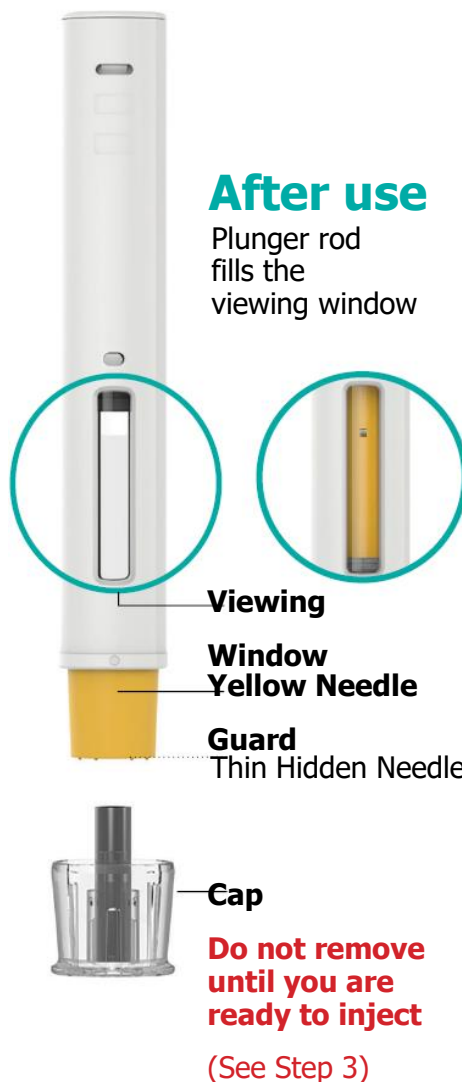
- 1 or 2 Pushpens based on the dose prescribed by your doctor

Not provided in the carton:

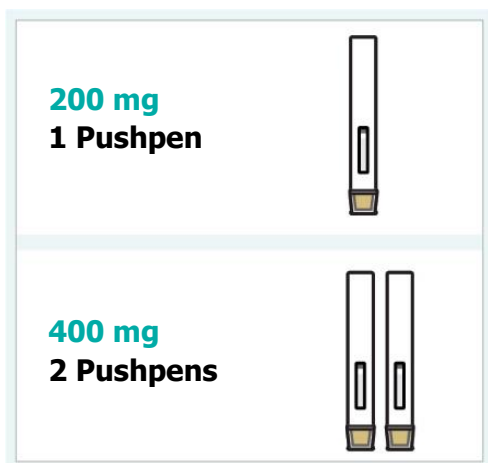
- Alcohol swabs
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps container (See Step 4)

After use

Plunger rod fills the viewing window



1. Get ready



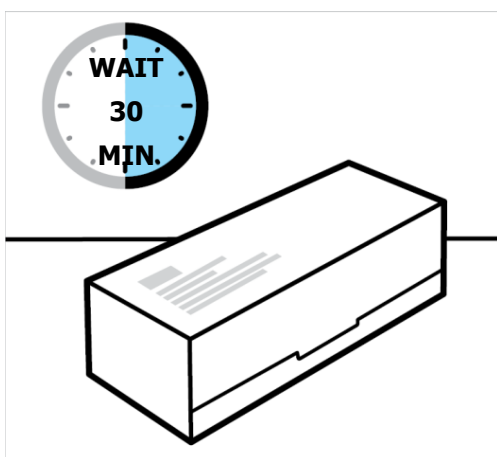
Check your prescribed dose to see if you will need to use 1 or 2 Pushpens and inspect carton(s)

Remove the carton(s) with the Pushpen from the refrigerator.

Check the expiration date ('Expiry') on the carton.

Do not use the Pushpen if the expiration date has passed or if the seal on the carton is broken.

Call your doctor or pharmacist for a new Pushpen.

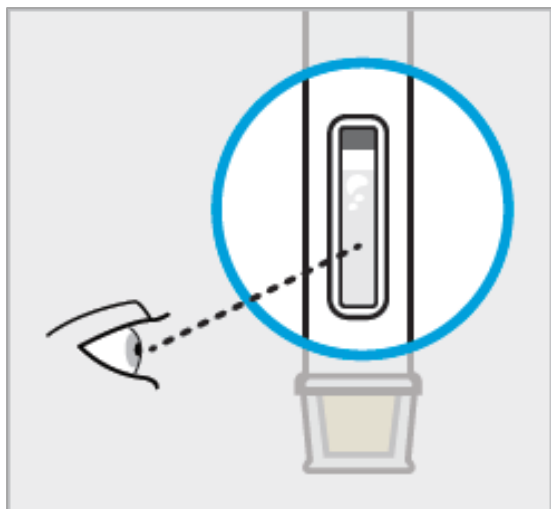


Allow TREMFYA to come to room temperature

Let the carton(s) sit on a flat surface at room temperature for approximately **30 minutes** before use.

Do not warm the Pushpen(s) any other way.

2. Prepare for your injection



Inspect liquid in window to see that it is clear to slightly yellow

Take the Pushpen 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 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 Pushpen.



Choose injection site

Select from the following areas for your injection:

- Front of thighs
- Lower stomach area (lower abdomen)

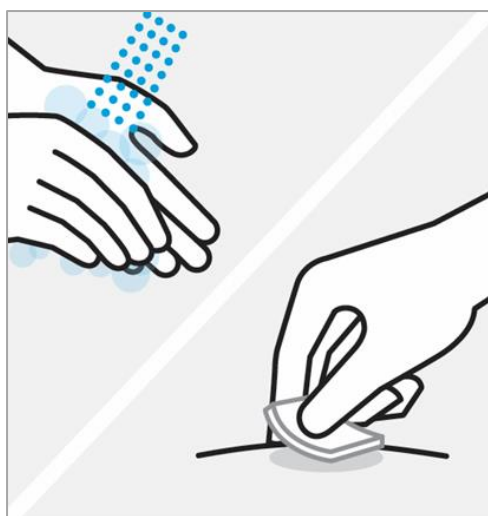
Do not use the 2-inch (5-centimeter) area around your belly-button.

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

If you need to give 2 injections to complete your dose, choose different areas or leave at least 2 inches (5-centimeters) between injection sites.

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

Avoid areas with scars or stretch marks.



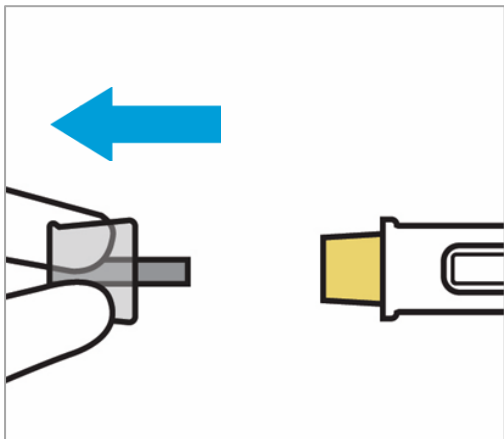
Wash hands and clean injection site

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.

3. Inject TREMFYA using the Pushpen



Remove cap when you are ready to inject

Do Not Touch Yellow Needle Guard!

This may start the injection and you will not receive the dose.

Pull the cap straight off. It is normal to see a few drops of liquid.

Inject TREMFYA within 5 minutes of removing cap.

Do not put the cap back on as this may damage the needle.

Do not use the Pushpen if it is dropped after removing the cap.

Call your doctor or pharmacist for a new Pushpen.



Position Pushpen straight onto the injection site then push and hold Pushpen

Do Not Lift The PushPen During Injection!

If you do, the yellow needle guard will lock and the full dose will not be delivered.

Position the Pushpen straight onto the injection site with the yellow needle guard against the skin and the viewing window facing you.

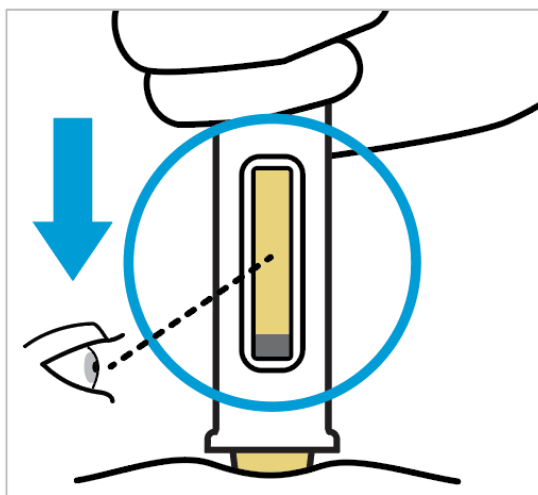
Press down on the Push pen and keep holding it down against the skin.

You will hear the first click.



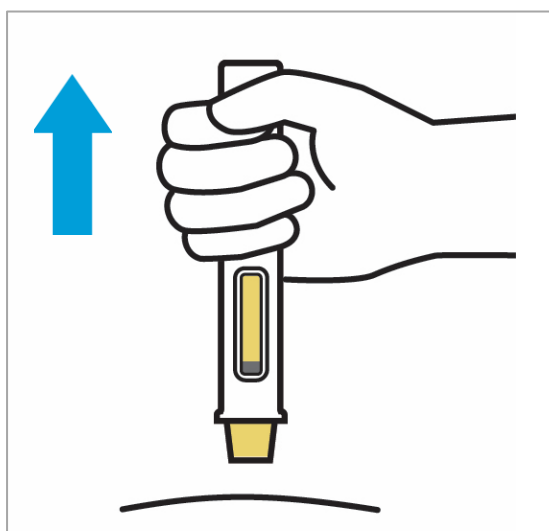
Keep holding the Pushpen firmly against the skin for about 10 seconds to hear a second click

You are almost done.



Keep holding firmly against the skin and confirm the injection is complete

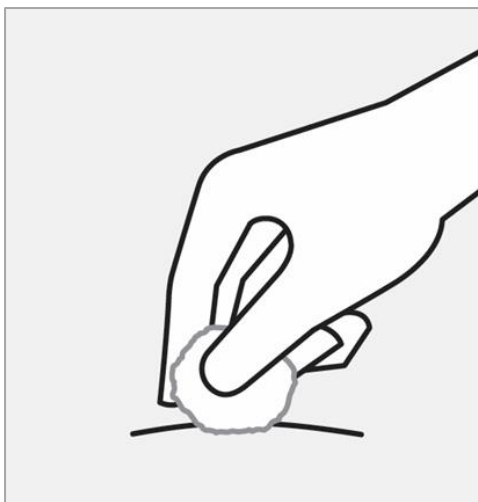
The injection is complete when the plunger rod stops moving and fills the viewing window.



Lift straight up

If your prescribed dose requires two injections, repeat Steps 2 to 4 with the second Pushpen.

4. After your injection



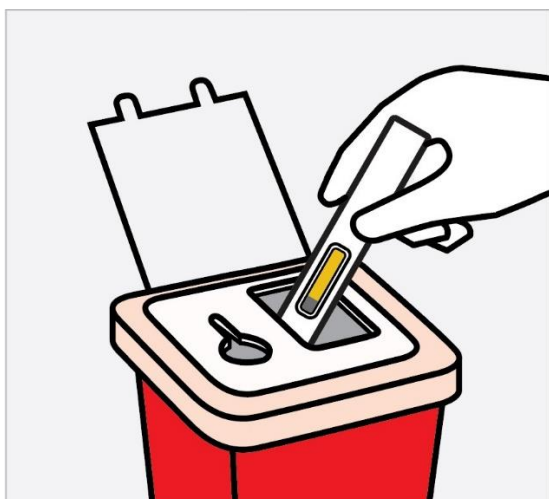
Check injection site

There may be a small amount of blood or liquid at the injection site.

Gently hold pressure over the injection site 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.

Your injection is now complete!



Throw away the used Pushpen and cap

Put your used Pushpen and cap 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 Pushpen in your household waste.

Do not recycle your used sharps disposal container.

Reference: 200 mg PushPen core IFU CCDS V.18, Aug 2024

List of excipients

Each TREMFYA 1 mL prefilled syringe or One-Press contains 100 mg guselkumab, L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection

Each TREMFYA 2 mL prefilled syringe or prefilled pen contains 200 mg guselkumab, L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection.

Special precautions for storage

TREMFYA is sterile and preservative-free. Discard any unused portion.

- Store in a refrigerator at 2°C to 8°C
- Store in original carton until time of use.
- Protect from light until use.
- Do not freeze.
- Do not shake.
- Not made with natural rubber latex.

Keep out of reach of children.

Nature and contents of container

Subcutaneous Injection

- TREMFYA 100 mg solution for injection in pre-filled syringe
1 mL solution in a pre-filled glass syringe with a fixed needle and a needle shield, assembled in an automatic needle guard.
TREMFYA is available in pack containing one pre-filled syringe.

- TREMFYA 100 mg solution for injection in One-Press
1 mL solution in a pre-filled glass syringe assembled in a One-Press with an automatic needle guard.
TREMFYA is available in a pack containing one One-Press and in a multipack containing 2 (2 packs of 1) One-press.
- TREMFYA 200 mg solution for injection in pre-filled syringe
2 mL solution in a pre-filled glass syringe with a fixed needle and a needle shield, assembled in an automatic needle guard.
TREMFYA is available in packs containing one prefilled syringe and in multipacks containing 2 (2 packs of 1) pre-filled syringes.
- TREMFYA 200 mg PushPen solution for injection in pre-filled pen
2 mL solution in a pre-filled glass syringe assembled in a pre-filled pen with an automatic needle guard.
TREMFYA is available in a pack containing one pre-filled pen and in a multipack containing 2 (2 packs of 1) pre-filled pens.

Not all pack sizes may be marketed.

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

DATE OF REVISION OF THE TEXT

100 mg Pre-filled syringe core IFU Nov 2016

100 mg One-Press core IFU CCDS V.18, Aug 2024

200 mg Pre-filled syringe core IFU CCDS V.16, Apr 2024

200 mg PushPen core IFU CCDS V.18, Aug 2024

Imported by

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

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