

Instructions for Use

TREMFYA[®] (trem fye´ ah) (guselkumab)

Prefilled Syringe

Important

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

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 prefilled syringe before attempting to inject. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.

Read this Instructions for Use before using your TREMFYA prefilled syringe and each time you get a refill. 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.

The TREMFYA prefilled 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 **36° to 46°F** (2° to 8°C).

Do not freeze TREMFYA prefilled syringe.

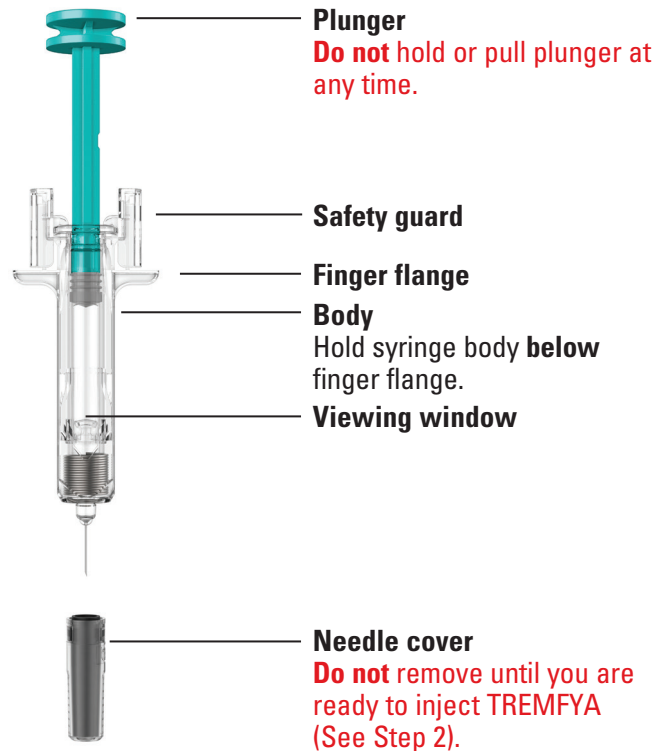
Keep TREMFYA prefilled syringe and all medicines out of reach of children.

Do not shake your TREMFYA prefilled syringe.

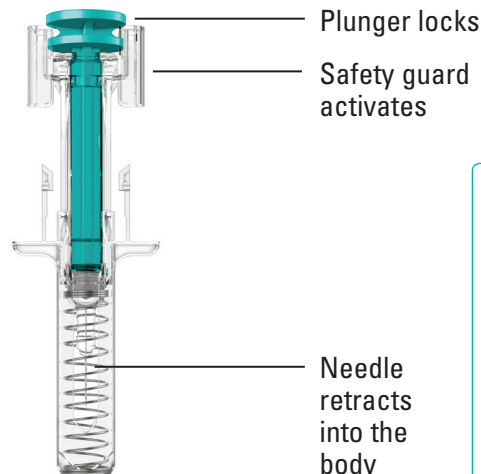
Keep TREMFYA prefilled syringe in the original carton to protect from light and physical damage.

Prefilled syringe parts

Before use



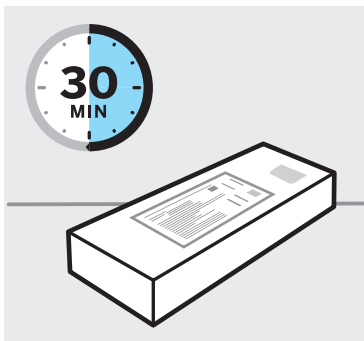
After use



You will need these supplies:

- **1 TREMFYA prefilled syringe**
- **Not provided in the TREMFYA prefilled syringe carton:**
- **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 your TREMFYA prefilled syringe carton from the refrigerator. Keep the prefilled 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 the prefilled syringe any other way.

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

Do not use your prefilled syringe if the expiration date has passed.

Do not inject TREMFYA if the perforations on the carton are broken. Call your healthcare provider or pharmacist for a refill.

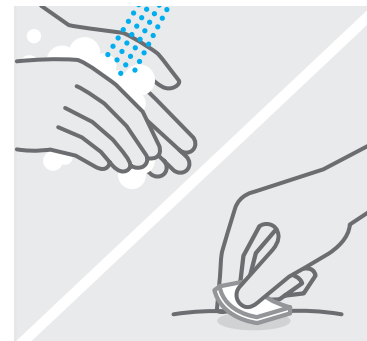


Choose injection site

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.

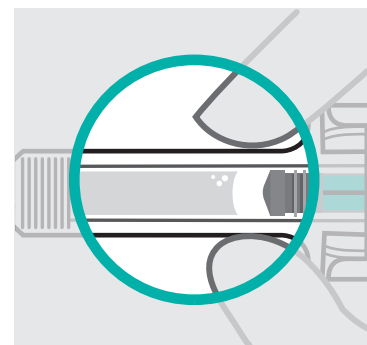


Clean injection site

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.



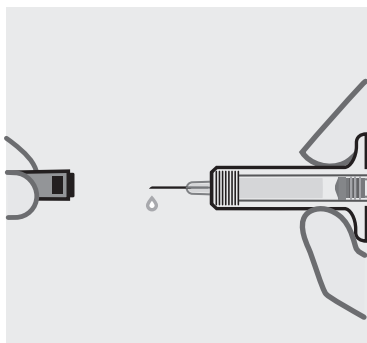
Inspect liquid

Take your TREMFYA prefilled syringe out of the carton.

Check the TREMFYA prefilled syringe 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. Call your healthcare provider or pharmacist for a refill.

2. Inject TREMFYA using prefilled syringe



Remove needle cover

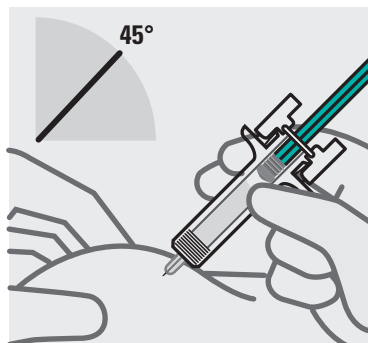
Hold your prefilled syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

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 a TREMFYA prefilled syringe if it is dropped. Call your healthcare provider or pharmacist for a refill.



Position fingers and insert needle

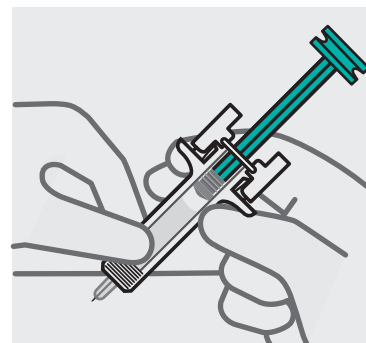
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

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.

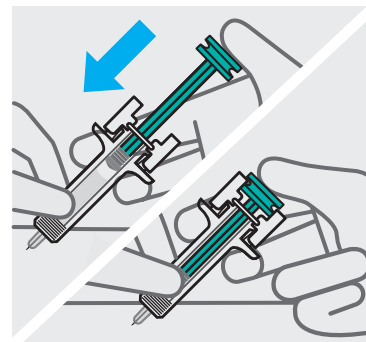
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



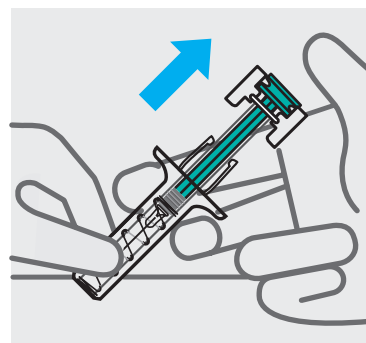
Release pinch and reposition hand

Use your free hand to grasp the body of the prefilled 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



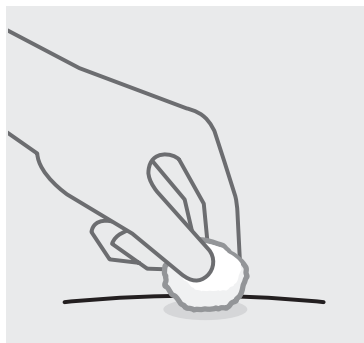
Dispose of your prefilled syringe

Put your used TREMFYA prefilled syringe in an FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your TREMFYA prefilled syringe in your household trash.

Do not recycle your used sharps disposal container.

For more information, see “How should I dispose of the used prefilled syringe?”



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.



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).

How should I dispose of the used prefilled syringe?

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

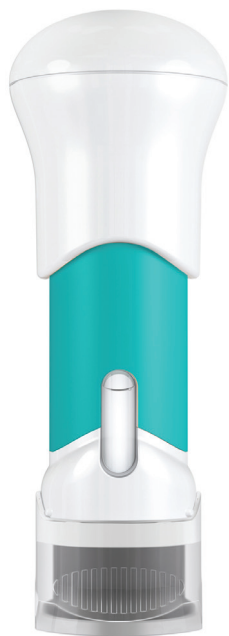
Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044
US License No. 1864



Instructions for Use

TREMFYA[®] (trem fye´ ah) (guselkumab)

One-Press Patient-Controlled Injector



SINGLE-DOSE

Important

TREMFYA comes in a single-dose One-Press injector containing one 100 mg 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.

Keep your One-Press injector and all medicines out of reach of children.

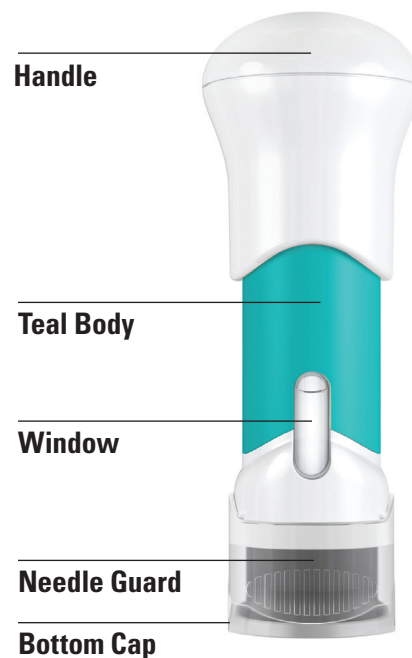
Do not shake your One-Press injector.

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).

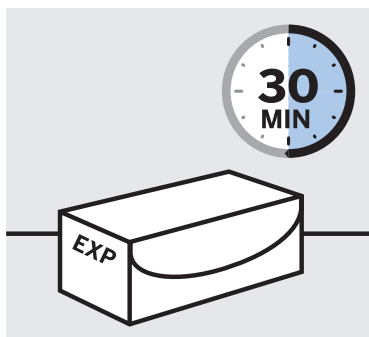
One-Press injector parts



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. Prepare for your injection



Inspect carton

Remove your One-Press injector carton from the refrigerator.

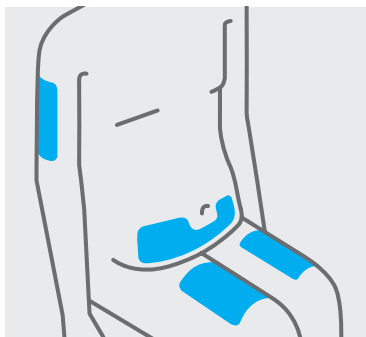
Keep your One-Press injector in the carton and let it sit on a flat surface at room temperature for **at least 30 minutes** before use.

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 perforations on the carton are broken. Call your healthcare provider or pharmacist for a new One-Press injector.

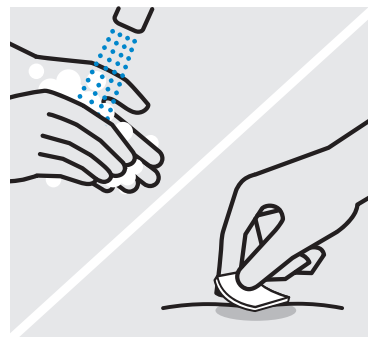


Choose injection site

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.



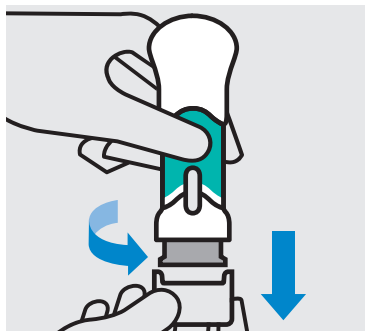
Inspect liquid in window

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 or discolored, or has large particles. Call your healthcare provider or pharmacist for a new One-Press injector.

2. Inject TREMFYA using the One-Press injector



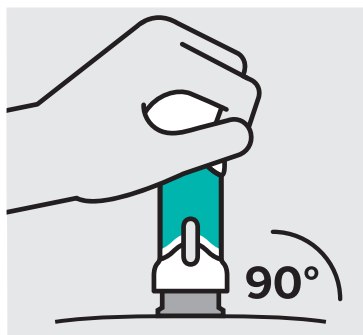
Twist and pull off bottom cap

Keep hands away from the needle guard after the cap is removed.

Inject TREMFYA within 5 minutes of removing the cap.

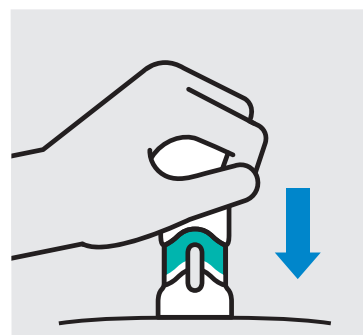
Do not put the cap back on, this could damage the needle.

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 on skin

Position the One-Press injector straight onto the skin (about 90 degrees relative to injection site).



Push handle straight down

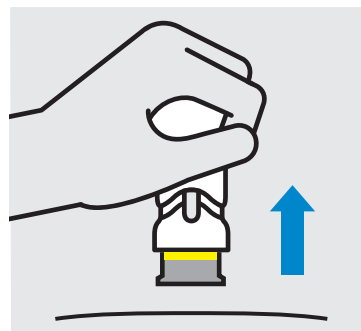
Medication injects as you push. Do this at a speed that is comfortable for you.

Do not lift the One-Press injector during the injection. The needle guard will lock and the full dose will not be delivered.



Complete injection

Injection is complete when the handle is pushed all the way down, you hear a click, and the teal body is no longer visible.



Lift straight up

The yellow band indicates that the needle guard is locked.

3. After your injection



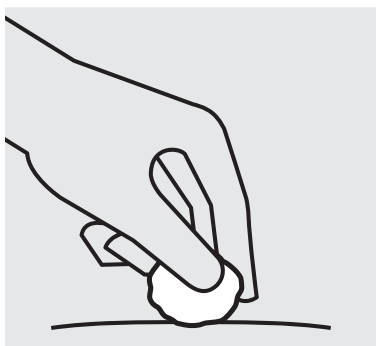
Dispose of your One-Press injector

Put your used One-Press injector in an FDA-cleared 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 “How should I dispose of the used One-Press injector?”.



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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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044
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