

Instructions for Use

TREMFYA® (trem fye´ ah) (guselkumab)

Prefilled Syringe



SINGLE-DOSE

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.

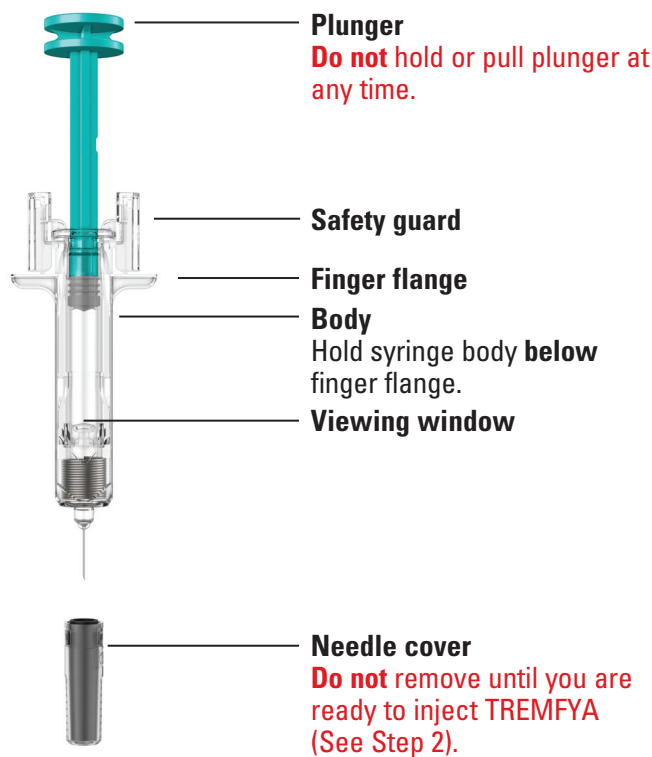
Keep TREMFYA prefilled syringe and all medicines out of reach of children.

Do not shake your TREMFYA prefilled syringe.

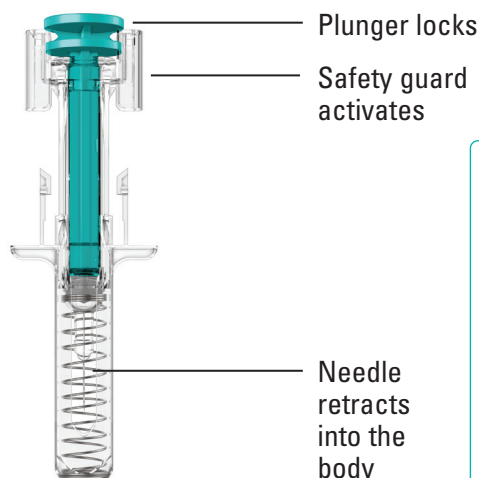
Keep TREMFYA prefilled syringe in the original carton to protect from light and physical damage.

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.

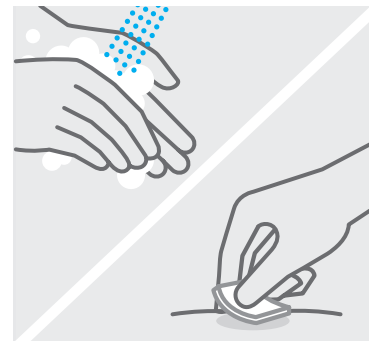


Choose injection site

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.

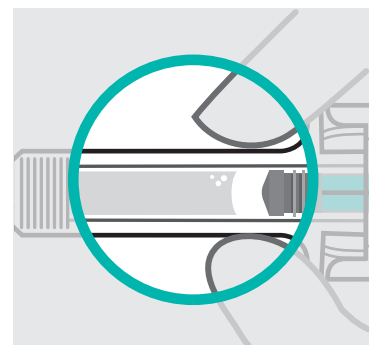


Clean injection site

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.



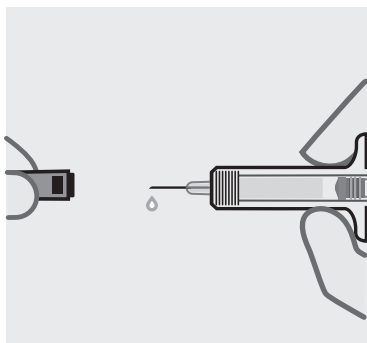
Inspect liquid

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

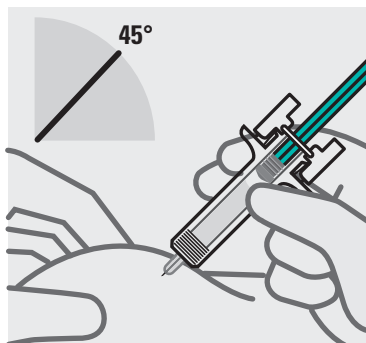
Hold your prefilled syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

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

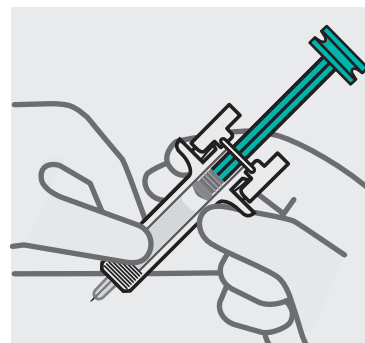
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

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.

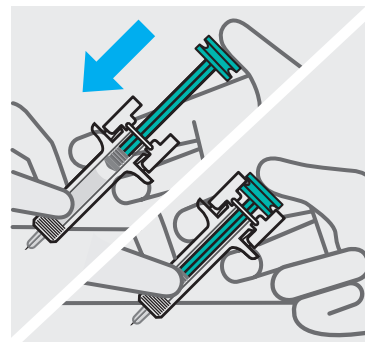
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

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



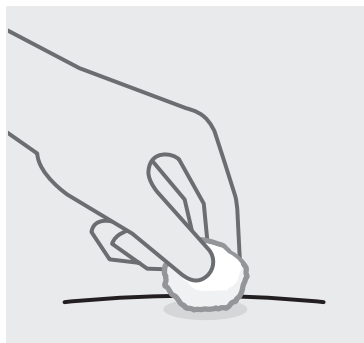
Dispose of your prefilled syringe

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

Approved: December 2017

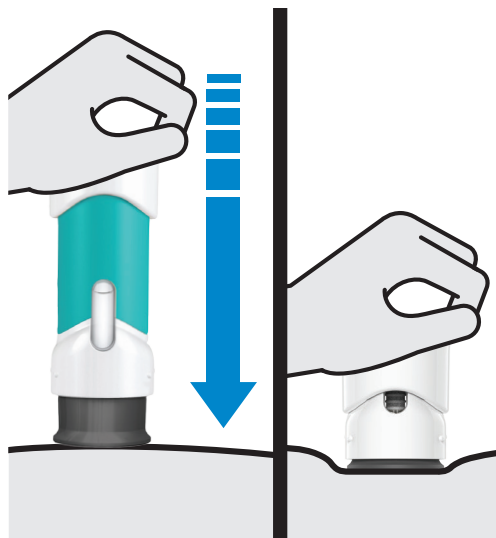
INSTRUCTIONS FOR USE

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.

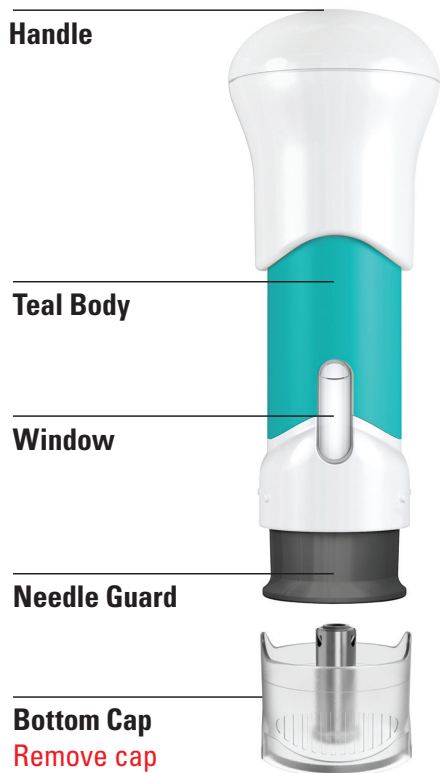
Keep your One-Press injector in the original carton to protect from light and physical damage.

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



Handle

Teal Body

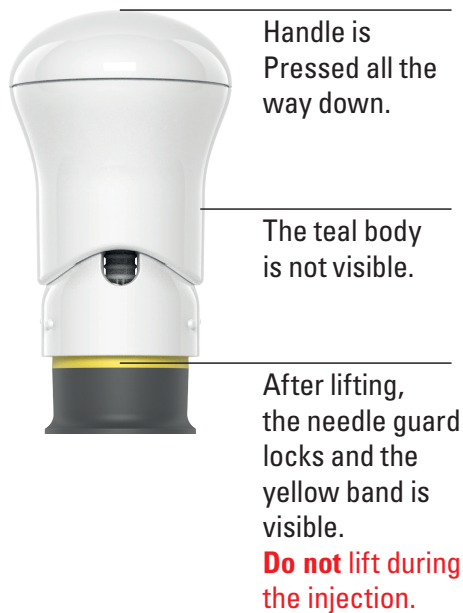
Window

Needle Guard

Bottom Cap

Remove cap
before injecting
(see Step 2).

After use



Handle is
Pressed all the
way down.

The teal body
is not visible.

After lifting,
the needle guard
locks and the
yellow band is
visible.

Do not lift during
the injection.

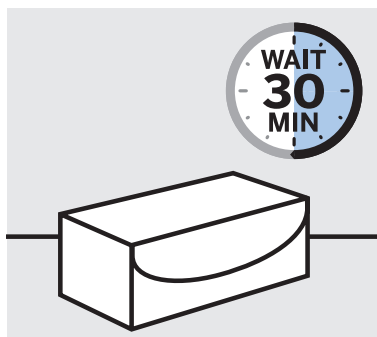
You will need:

- 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

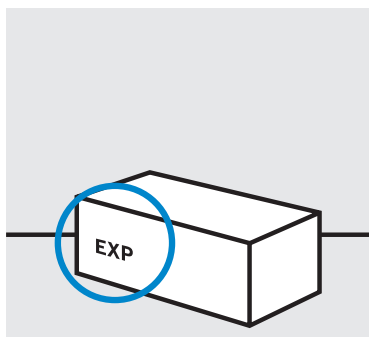


Inspect carton and allow TREMFYA to come to room temperature

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.



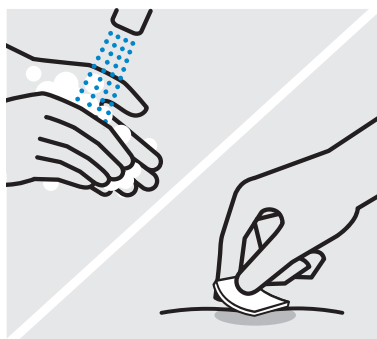
Choose injection site

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.

1. Preparing to Inject TREMFYA (continued)



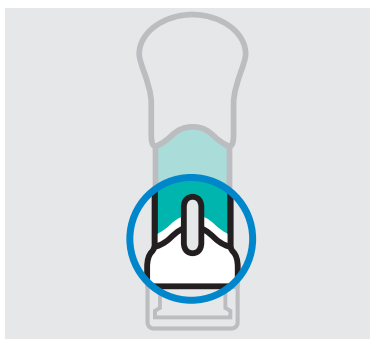
Wash hands

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.

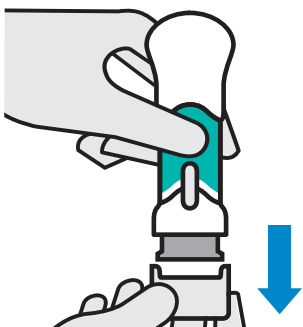
Check the liquid in the window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see one or more air bubbles. This is normal.

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



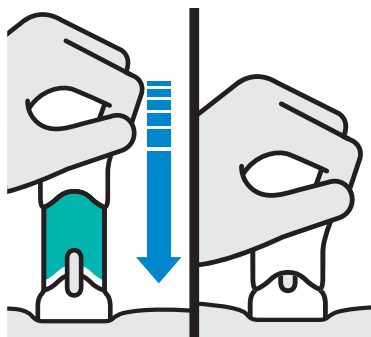
Pull off bottom cap

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

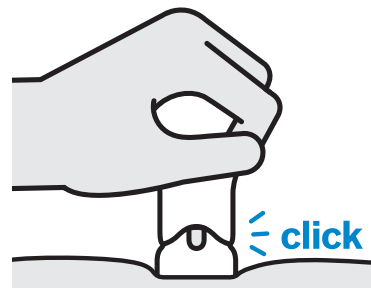
DO NOT LIFT ONE-PRESS during injection!

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.

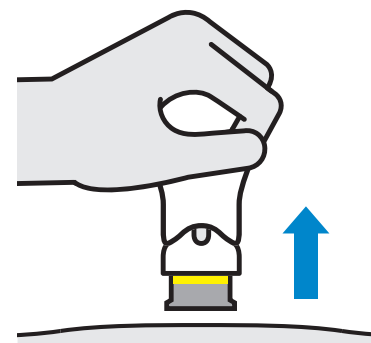
The medication injects as you push. Do this at a speed that is comfortable for you.



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. You may also consult your pharmacist.

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

Revised: June 2023

Instructions for Use

TREMFYA® (trem fye´ ah) (guselkumab)

injection, for subcutaneous use

200 mg/2mL (100 mg/mL) Prefilled Syringe

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 prefilled syringe containing one 200 mg dose.

Your healthcare provider will tell you if you will need to use 1 or 2 prefilled syringes.

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 correct way to prepare and inject TREMFYA before using the prefilled syringe.

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.

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

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 device and lock into place.



Storage information

Store in refrigerator between **36°F to 46°F** (2°C to 8°C).

Do not freeze TREMFYA prefilled syringe.

Do not shake your TREMFYA prefilled syringe.

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

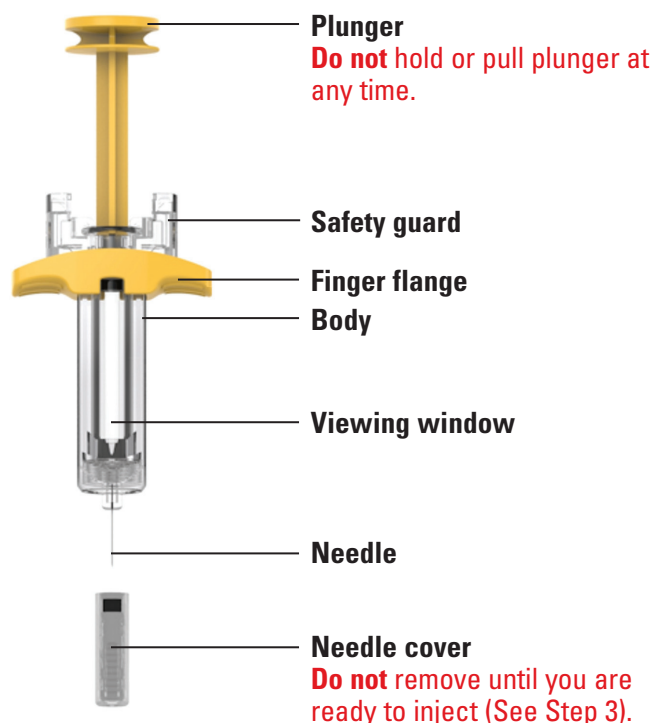
Keep TREMFYA prefilled syringe in the original carton to protect from light and physical damage.



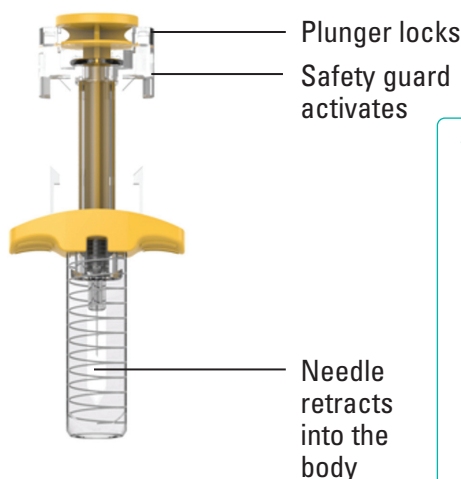
SINGLE-DOSE

Prefilled syringe parts

Before use



After use



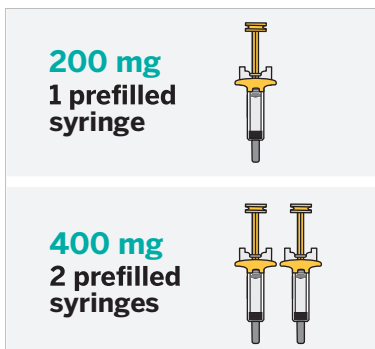
You will need:

- 1 or 2 prefilled syringes based on the dose prescribed by your Healthcare Provider

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 prefilled syringes and inspect carton(s)

Remove the carton(s) from the refrigerator.

Check the expiration ('EXP') date.

Do not use your prefilled syringe if the expiration date has passed or if the seal on the carton is broken. Contact your healthcare provider or pharmacist for a new prefilled syringe.

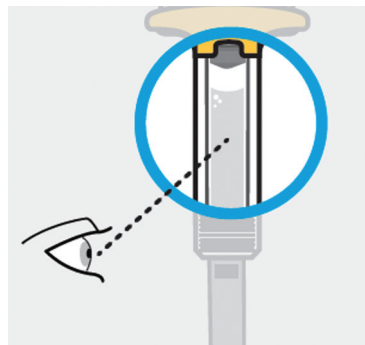


Allow TREMFYA to come to room temperature

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

Do not warm the prefilled syringe(s) any other way.

2. Prepare to inject TREMFYA



Take the prefilled syringe out of the carton.

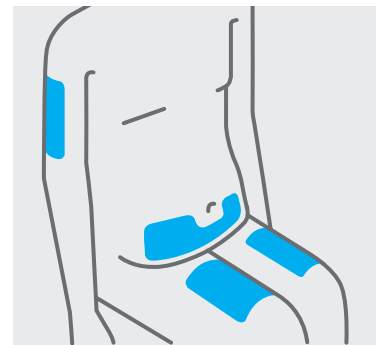
Inspect liquid to see that it is clear and colorless to slightly yellow

Check the liquid in the viewing window. It should be clear and colorless 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 prefilled syringe if it is dropped. Call your healthcare provider or pharmacist for a new prefilled syringe.



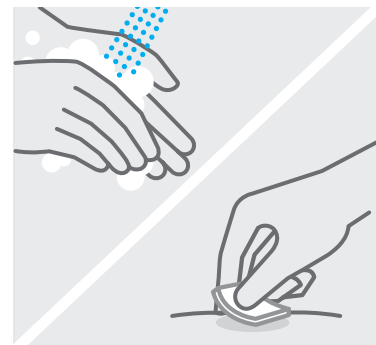
Choose injection site

Select a site from the following areas for your injection:

- Front of thighs
- 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)

If you need to give 2 injections to complete your dose, choose different areas or leave at least 2 inches 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



Remove needle cover when you are ready to inject

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

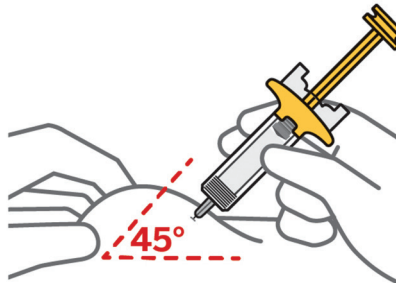
Inject TREMFYA within 5 minutes of removing the needle cover.

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

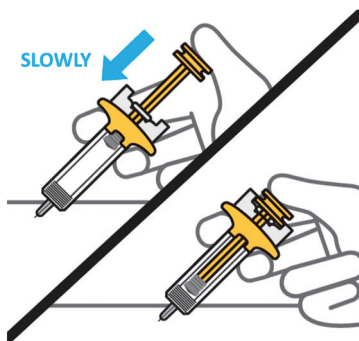
Do not hold or pull the plunger at any time.



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

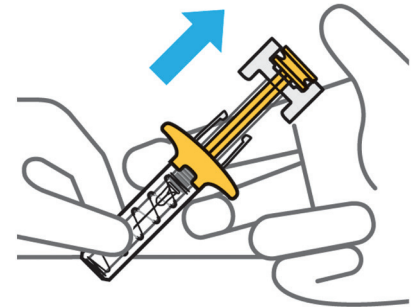
It is important to pinch enough skin to inject under the skin and not into muscle.

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.

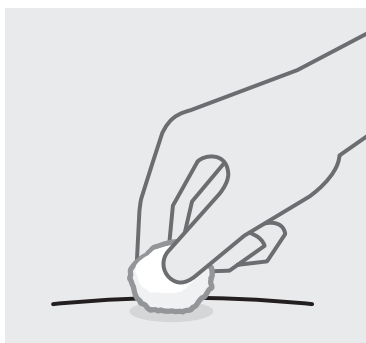


Release pressure from plunger to remove the needle from the skin

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 prefilled syringe.

4. After your injection

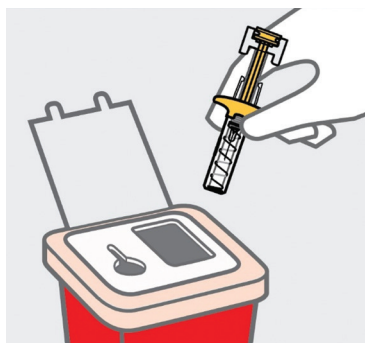


Check injection site

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.



Dispose of your prefilled syringe

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

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

Do not recycle your used sharps disposal container.

For more information, see Disposing of TREMFYA prefilled syringe.

Disposing of TREMFYA prefilled syringe

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of 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. You may also consult your pharmacist.



Need help?

Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback, call 800-526-7736.

Manufactured by:
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Horsham, PA 19044, USA
US License No. 1864

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

Approved: March / 2025

INSTRUCTIONS FOR USE

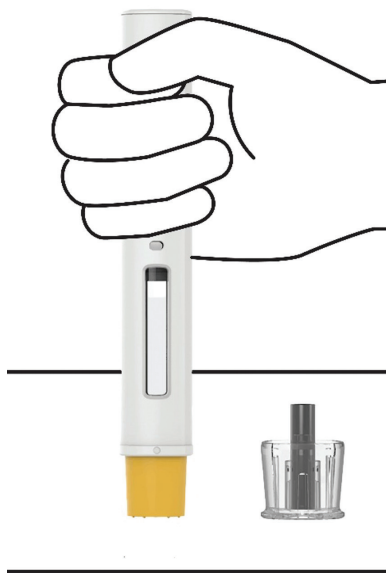
TREMFYA® PEN [trem fye' ah Pen]

(guselkumab)

injection, for subcutaneous use

200 mg/2 mL Prefilled Pen

This Instructions for Use contains information on how to inject with TREMFYA PEN.



SINGLE-DOSE

Important Information You Need to Know Before Injecting with TREMFYA PEN

TREMFYA PEN comes in a single-dose Prefilled Pen containing one 200 mg dose.

Your healthcare provider will tell you if you will need to use 1 or 2 Prefilled Pens.

If your healthcare provider decides that you or a caregiver may be able to give your injections with TREMFYA PEN at home, you should receive training on the correct way to prepare and inject with TREMFYA PEN before using the Prefilled Pen.

Read this Instructions for Use before using your Prefilled Pen and each time you get a new Prefilled Pen. 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.

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



Storage information

Store in refrigerator between **36 °F to 46 °F** (2 °C to 8 °C).

Do not freeze your TREMFYA PEN.

Do not shake your TREMFYA PEN.

Keep your TREMFYA PEN and all medicines out of reach of children.

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

TREMFYA PEN parts

Before use

After use

Plunger rod fills the viewing window

Viewing Window

Yellow Needle Guard

Thin Hidden Needle

Cap

Do not remove until you are ready to inject (See Step 3)

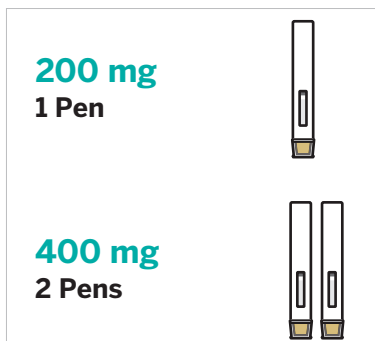
You will need:

- 1 or 2 Prefilled Pens based on the dose prescribed by your Healthcare Provider

Not provided in the carton:

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

1. Get ready

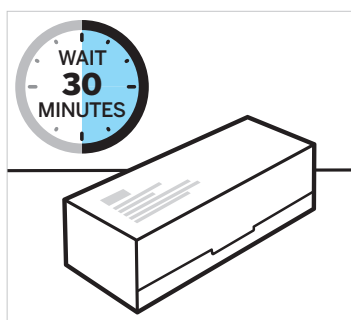


Check your prescribed dose to see if you will need to use 1 or 2 Prefilled Pens and inspect carton(s)

Remove the carton(s) from the refrigerator.

Check the expiration ('EXP') date.

Do not use the Prefilled Pen if the expiration date has passed or if the seal on the carton is broken. Contact your healthcare provider or pharmacist for a new Prefilled Pen.

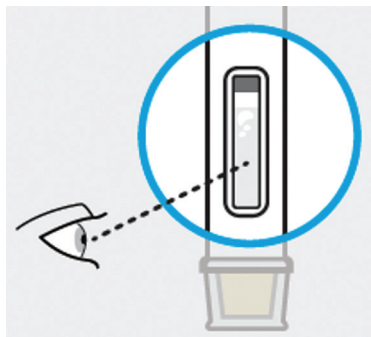


Allow TREMFYA PEN to come to room temperature

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

Do not warm the Prefilled Pen(s) any other way.

2. Prepare to inject with TREMFYA PEN



Take your Prefilled Pen out of the carton.

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

Check the liquid in the viewing window. It should be clear and colorless 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

Call your healthcare provider or pharmacist for a new Prefilled Pen.



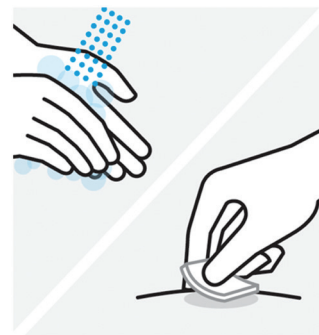
Choose injection site

Select from the following areas for your injection:

- Front of thighs
- 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)

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

Do not inject into skin that is tender, bruised, red, scaly, thick or hard. Avoid areas with scars or stretch marks.



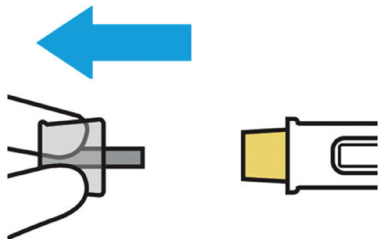
Wash hands and clean injection site

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 with TREMFYA PEN



Remove cap when you are ready to inject

Do Not Touch Yellow Needle Guard!

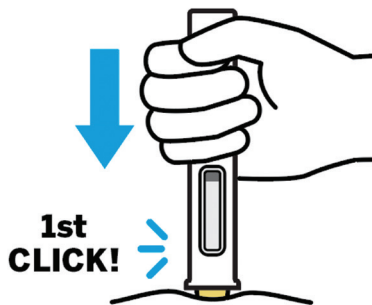
This may start the injection and you will not receive the dose.

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

Inject with TREMFYA PEN within 5 minutes of removing cap.

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

Do not use your Prefilled Pen if it is dropped after removing the cap. Call your healthcare provider or pharmacist for a new Prefilled Pen.



Position the Prefilled Pen straight onto the injection site then push and hold the Prefilled Pen

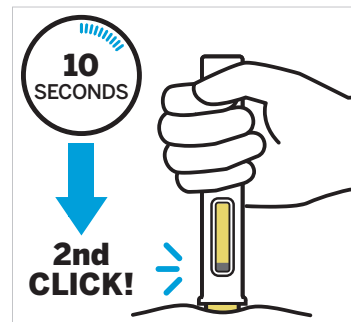
Do Not Lift The Prefilled Pen During Injection!

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

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

Press down on the Prefilled Pen and keep holding it down against the skin.

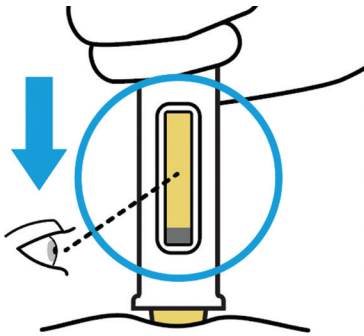
You will hear the first click.



Keep holding your Prefilled Pen firmly against the skin for about 10 seconds to hear a second click

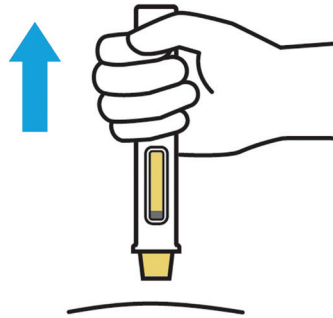
You are almost done.

3. Inject with TREMFYA PEN (continued)



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

Your 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 Prefilled Pen.

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.



Dispose of your Prefilled Pen and cap

Put your used Prefilled Pen and cap in an FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your Prefilled Pen in your household trash.

Do not recycle your used sharps disposal container.

For more information, see Disposing of TREMFYA PEN.

Disposing of TREMFYA PEN

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of 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. You may also consult your pharmacist.



Need help?

Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback, call 800-526-7736.

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

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

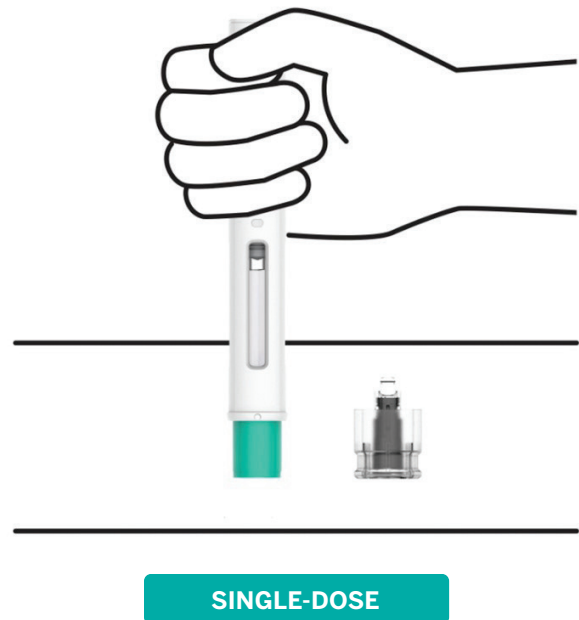
Approved: March / 2025

INSTRUCTIONS FOR USE TREMFYA® PEN [trem fye' ah Pen] (guselkumab)

injection, for subcutaneous use

100 mg/mL Prefilled Pen

This Instructions for Use contains information on how to inject with TREMFYA PEN.



Important Information You Need to Know Before Injecting with TREMFYA PEN

TREMFYA PEN comes in a single-dose Prefilled Pen containing one 100 mg dose.

If your healthcare provider decides that you or a caregiver may be able to give your injections with TREMFYA PEN at home, you should receive training on the correct way to prepare and inject with TREMFYA PEN before using the Prefilled Pen.

Read this Instructions for Use before using your Prefilled Pen and each time you get a new Prefilled Pen. 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.

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

Storage information

Store in refrigerator between **36 °F to 46 °F** (2 °C to 8 °C).

Do not freeze your TREMFYA PEN.

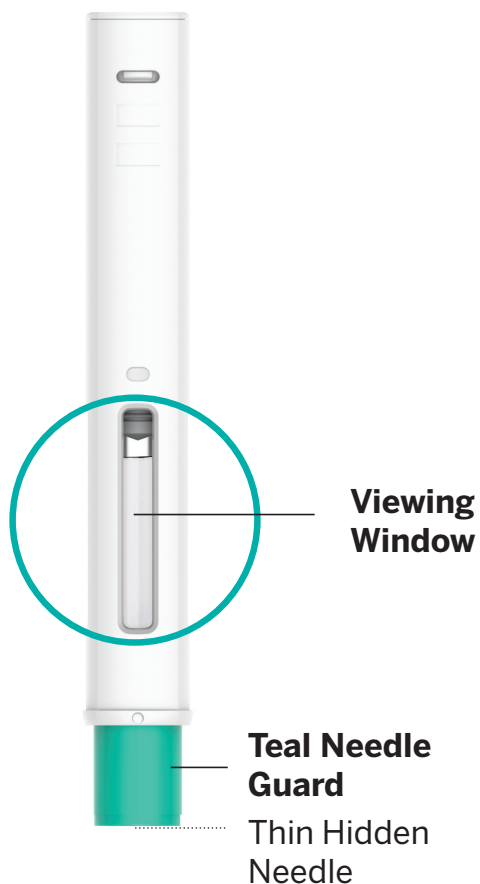
Do not shake your TREMFYA PEN.

Keep your TREMFYA PEN and all medicines out of reach of children.

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

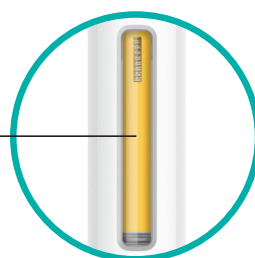
TREMFYA PEN parts

Before use



After use

Yellow Plunger rod fills the viewing window



Do not remove until you are ready to inject (See Step 3)

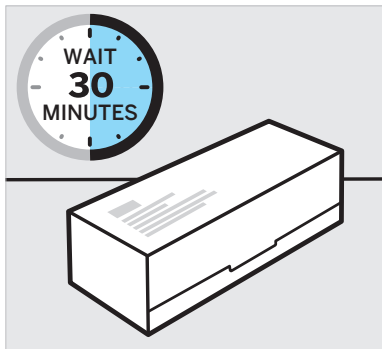
You will need:

- 1 Prefilled Pen

Not provided in the carton:

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

1. Get ready



Allow TREMFYA PEN to come to room temperature and inspect carton

Remove the carton from the refrigerator and let the carton sit on a flat surface at room temperature for approximately **30 minutes** before use.

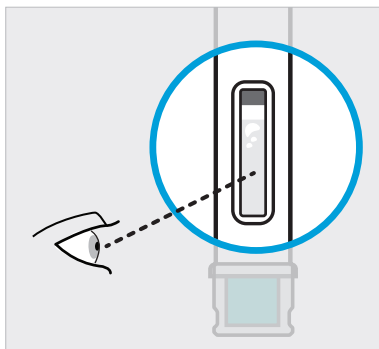
Do not warm the Prefilled Pen any other way.

Check to see that you have the correct medicine and dose.

Check the expiration ('EXP') date.

Do not use the Prefilled Pen if the expiration date has passed or if the seal on the carton is broken. Contact your healthcare provider or pharmacist for a new Prefilled Pen.

2. Prepare to inject with TREMFYA PEN



Take your Prefilled Pen out of the carton.

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

Check the liquid in the viewing window. It should be clear and colorless 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

Call your healthcare provider or pharmacist for a new Prefilled Pen.

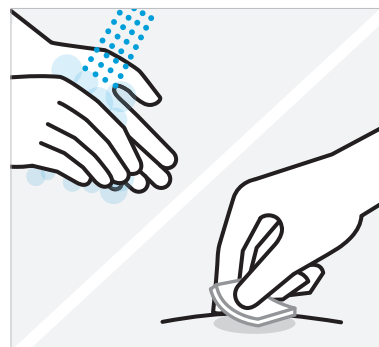


Choose injection site

Select from the following areas for your injection:

- Front of thighs
- 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, scaly, thick or hard. Avoid areas with scars or stretch marks.



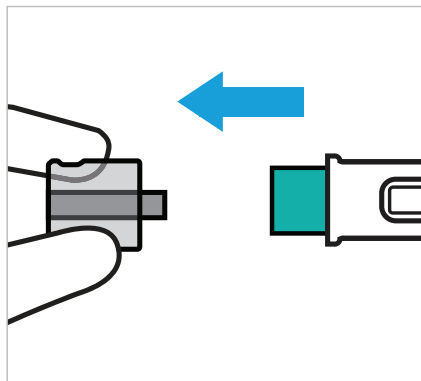
Wash hands and clean injection site

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 with TREMFYA PEN



Remove cap when you are ready to inject

Do Not Touch Teal 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 with TREMFYA PEN within 5 minutes of removing cap.

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

Do not use your Prefilled Pen if it is dropped after removing the cap. Call your healthcare provider or pharmacist for a new Prefilled Pen.



Position the Prefilled Pen straight onto the injection site then push and hold the Prefilled Pen

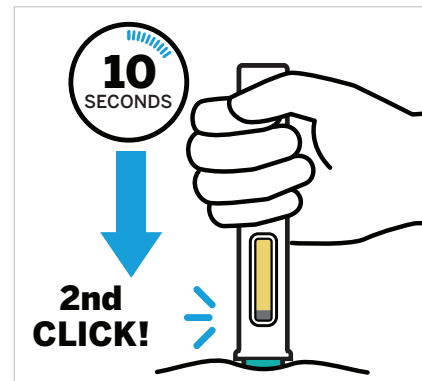
Do Not Lift The Prefilled Pen During Injection!

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

Position your Prefilled Pen straight onto the injection site with the teal needle guard against the skin and the viewing window facing you.

Press down on the Prefilled Pen and keep holding it down against the skin.

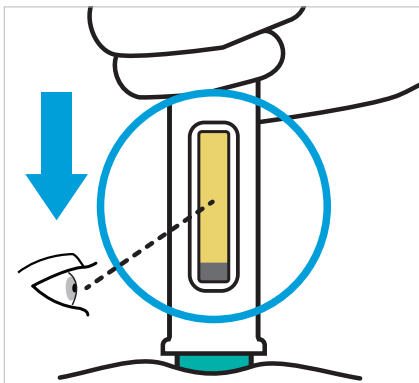
You will hear the first click.



Keep holding your Prefilled Pen firmly against the skin for about 10 seconds to hear a second click

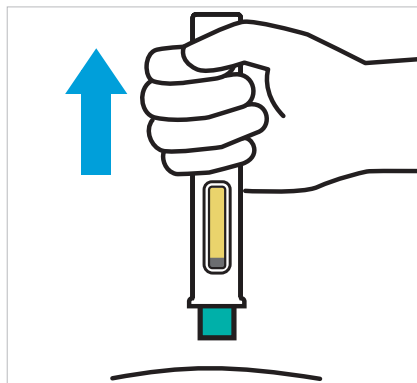
You are almost done.

3. Inject with TREMFYA PEN (continued)



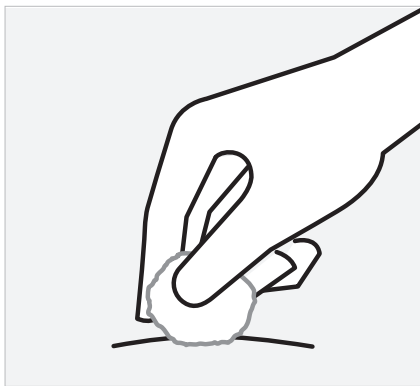
Keep holding firmly against the skin and confirm your injection is complete

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



Lift straight up

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.



Dispose of your Prefilled Pen and cap

Put your used Prefilled Pen and cap in an FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your Prefilled Pen in your household trash.

Do not recycle your used sharps disposal container.

For more information, see Disposing of TREMFYA PEN.

Disposing of TREMFYA PEN

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of 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. You may also consult your pharmacist.

Need help?

Call your healthcare provider to talk about any questions you may have. For additional assistance or to share your feedback, call 800-526-7736.

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Approved: March / 2025
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