

Instructions for use
Tremfya
Pre-filled syringe



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 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 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

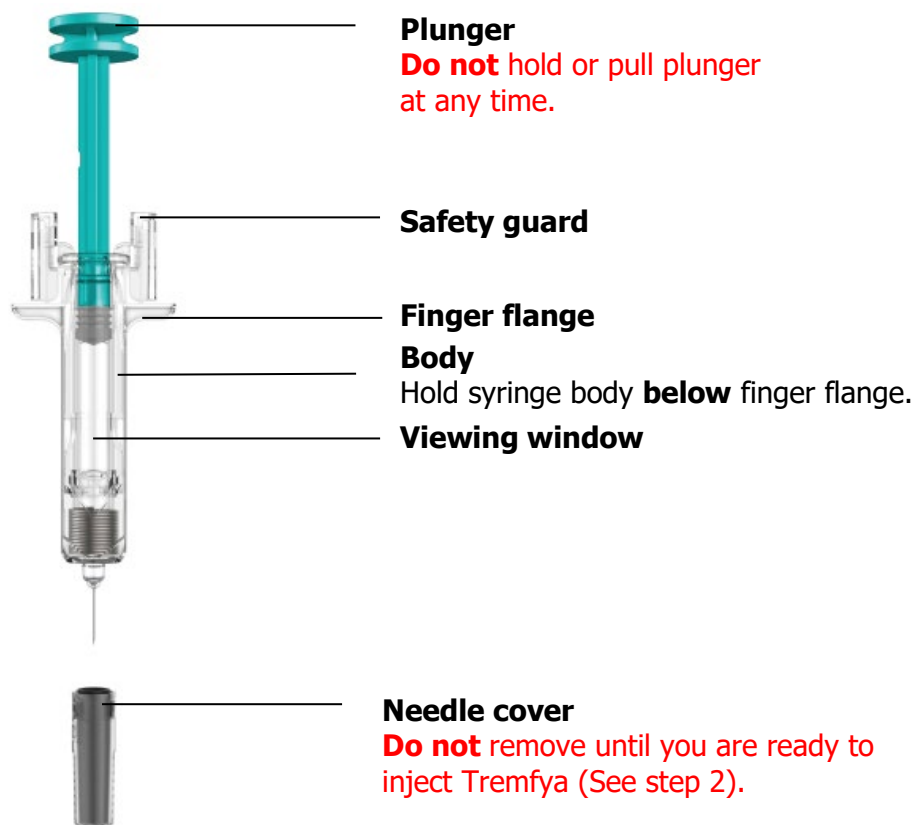
Store in refrigerator at 2° to 8°C. **Do not** freeze.

Keep Tremfya and all medicines out of reach of children.

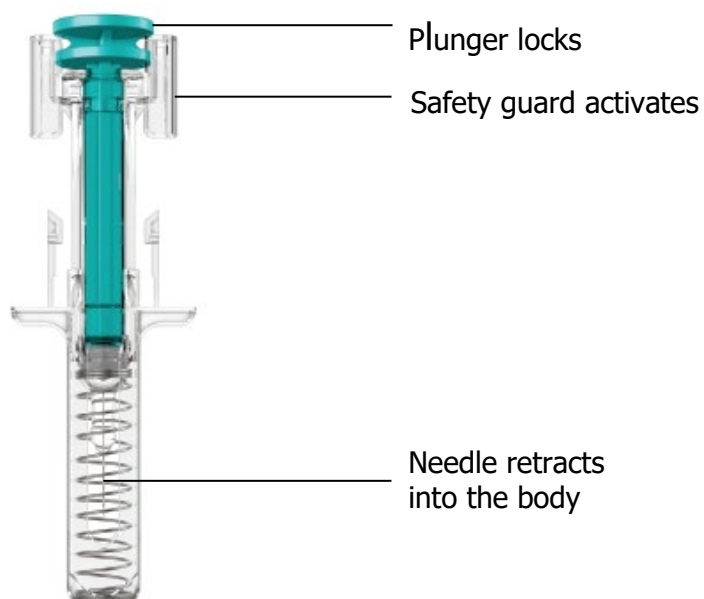
Do not shake the pre-filled syringe at any time.

Pre-filled syringe at-a-glance

Before injection



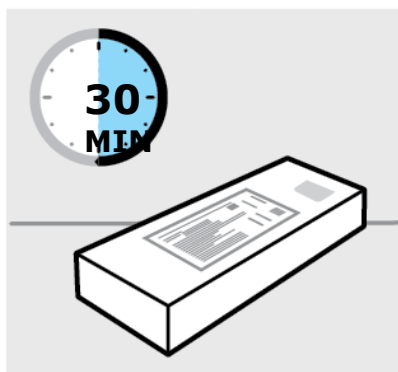
After injection



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 expiry 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:

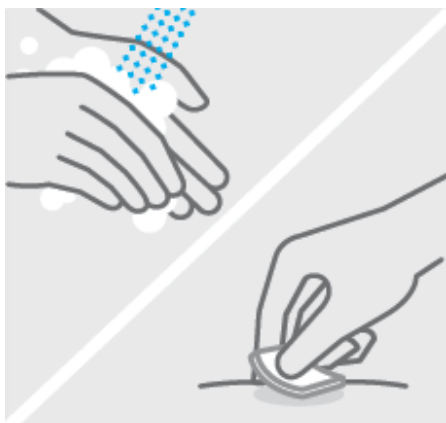
- **Front of thighs** (recommended)
- Lower abdomen

Do not use the 5-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 or hard.

Do not inject into areas with scars or stretch marks.

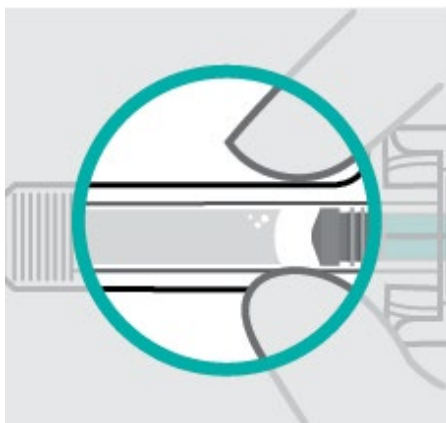


Clean injection site

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.



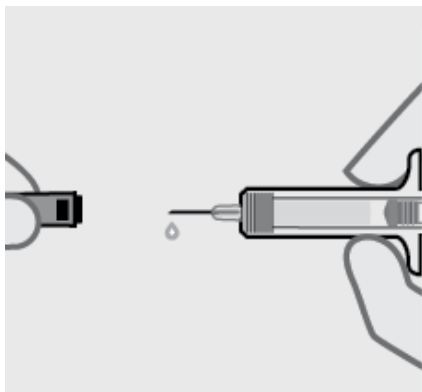
Inspect liquid

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 discoloured, 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

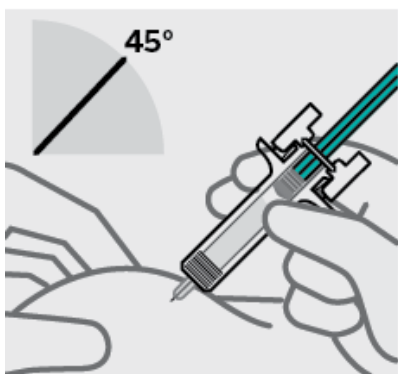
Hold syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

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

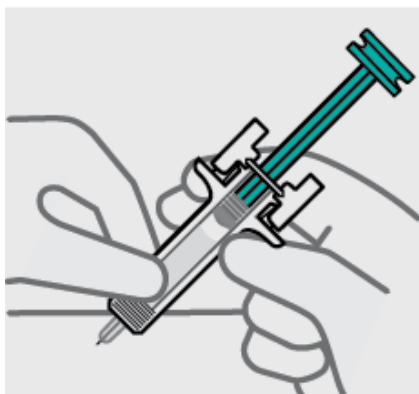
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

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.

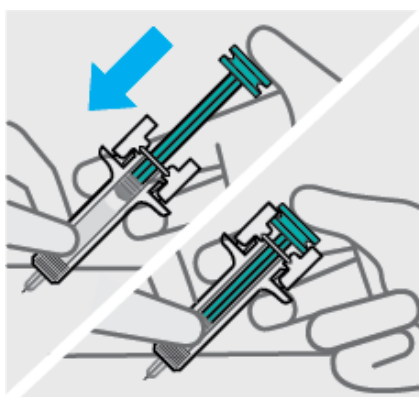
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



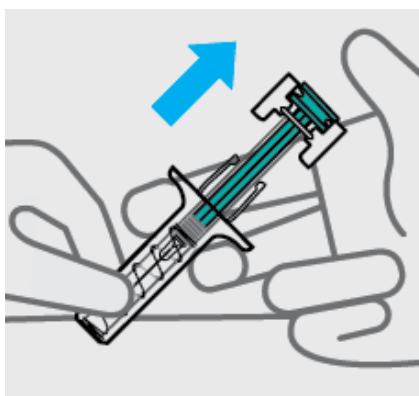
Release pinch and reposition hand

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.

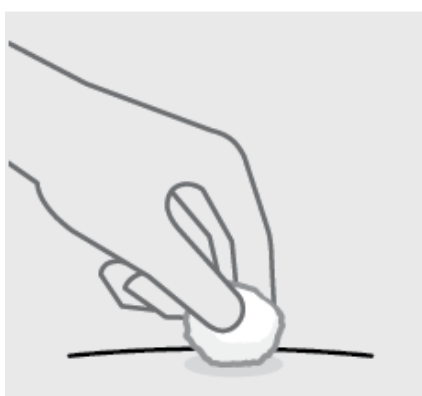
3. After your injection



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!



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.

Instructions for use Tremfya Pre-filled pen



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.



Storage information

Store in refrigerator at 2° to 8°C.

Do not freeze.

Keep Tremfya and all medicines out of reach of children.

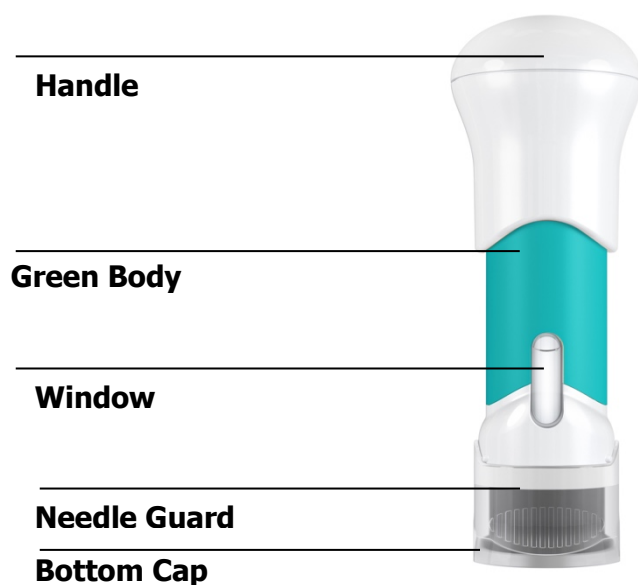
Do not shake your pre-filled pen at any time.



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.

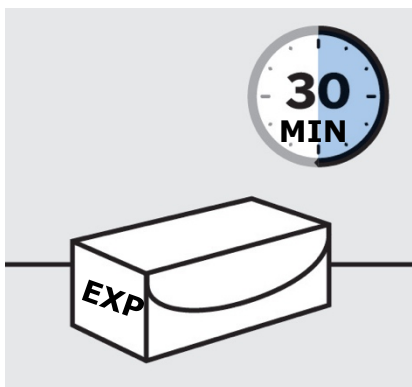
Pre-filled pen at-a-glance



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

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 **at least 30 minutes** before use.

Do not warm any other way.

Check the expiry date ('EXP') on the carton.

Do not use if the expiry date has passed.

Do not inject if perforations on the carton are broken.

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

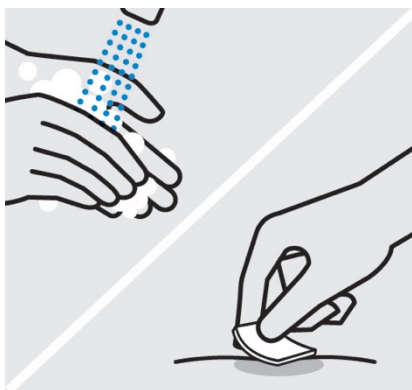


Choose injection site

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

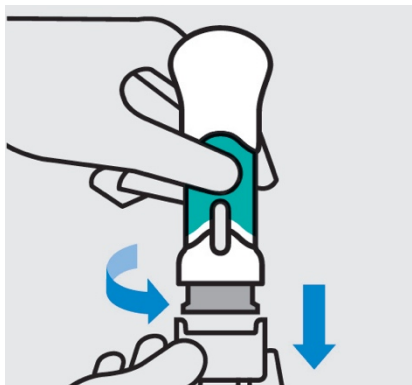
Take the pre-filled pen out of the carton.

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 discoloured, 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



Twist and pull off bottom cap

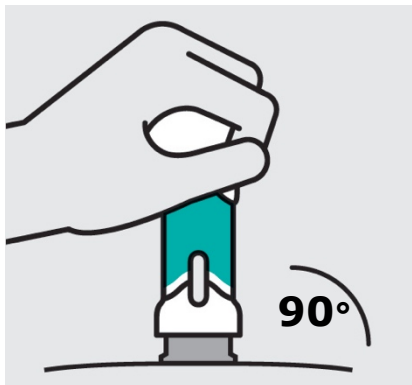
Keep hands away from the needle guard after the cap is removed.

Inject within 5 minutes of removing the cap.

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

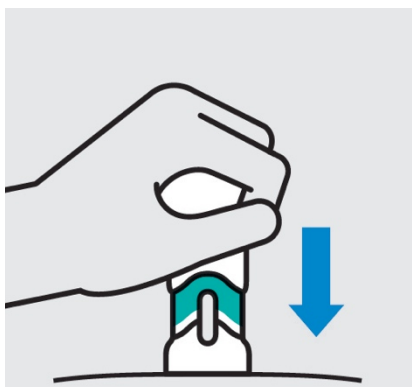
Do not use the pre-filled pen if it is dropped after removing the cap.

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



Place on skin

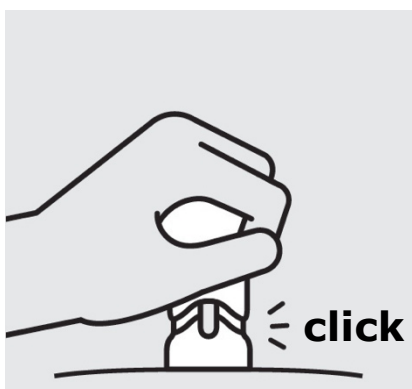
Position the pre-filled pen straight onto the skin (about 90 degrees relative to injection site).



Push handle straight down

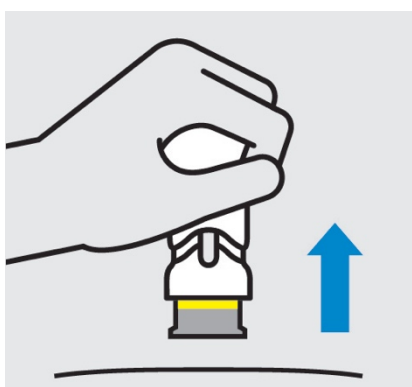
Medication injects as you push down. Do this at a speed that is comfortable for you.

Do not lift the pre-filled pen 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 green body is no longer visible.



Lift straight up

The yellow band indicates that the needle guard is locked.

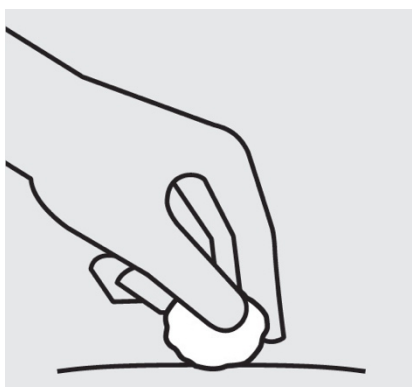
3. After your injection



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.



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

EU SmPC version Jul-2022 and Japan PI version Nov 2019 (PPP)_Editorial change

Imported by

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqjacth@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>