

Instructions for Use **TREMFYA®** (guselkumab) **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 this Instructions for Use before using the TREMFYA pre-filled syringe and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

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

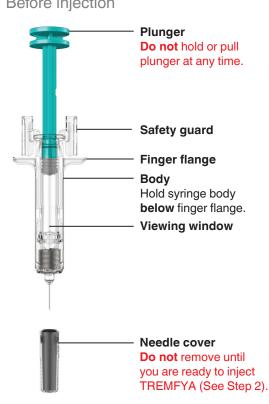
Store in refrigerator at 2° to 8°C. **Do not** freeze.

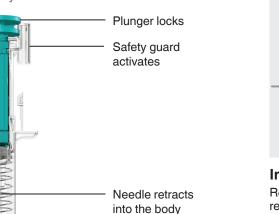
Keep TREMFYA pre-filled syringe and all medicines out of reach of children.

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

Pre-filled safety syringe at-a-glance

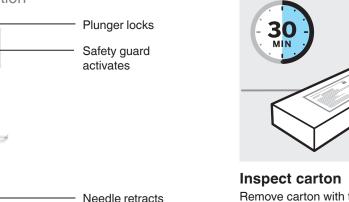
Before injection





- 1 Alcohol swab
- 1 Cotton ball or gauze pad
- 1 Sharps container (See Step 3)

After injection



You will need these supplies:

- 1 Adhesive bandage

1. Prepare for your injection



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 Call your doctor or pharmacist for a refill.

Do not inject into areas with scars or stretch marks.

3. After your injection

Select from the following areas for your injection:

• Lower abdomen (do not use the 5 centimetre

• Back of upper arms (if a caregiver is giving you the

Do not inject into skin that is tender, bruised, red,

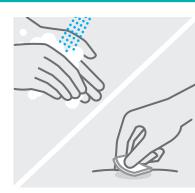
Choose injection site

injection)

scaly or hard.

• Front of thighs (recommended)

area around your belly-button

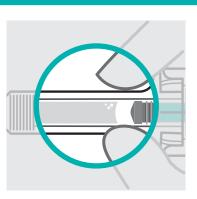


Clean injection site

swab and allow it to dry.

Wash your hands well with soap and warm water. Wipe your chosen injection site with an alcohol

Do not touch, fan or blow on the injection site after you have cleaned it.



Inspect liquid

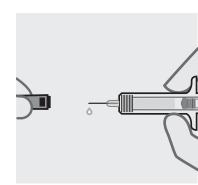
Take the pre-filled syringe out of the carton.

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. Call your doctor or pharmacist for a refill.

2. Inject TREMFYA using pre-filled syringe



Remove needle cover

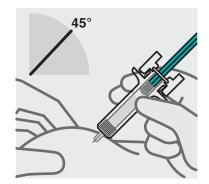
Hold syringe by the body and pull needle cover straight off.

It is normal to see a drop of liquid.

Inject within 5 minutes of removing the needle

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



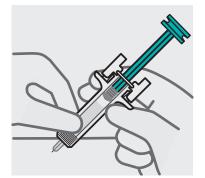
Position fingers and insert needle

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

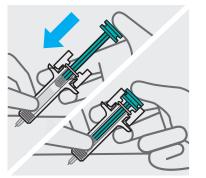
It is important to pinch enough skin to inject under the skin and not into the muscle.

Insert needle with a quick, dart-like motion.



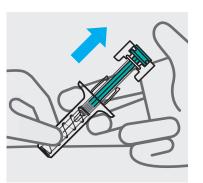
Release pinch and reposition hand

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



Release pressure from plunger

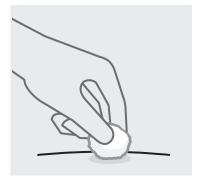
The safety guard will cover the needle and lock into place, removing the needle from your skin.



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!



call your doctor to talk about any questions you may have.

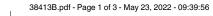
The Janssen Immunology Patient Support Program is available to patients prescribed TREMFYA. Call 1800 666 845

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a refill.







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Product Artwork CoE

Janssen **T**

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TREMFYA PCC 38413B

Template Ref. Name: Schaffhausen/IFU/3410/1 656x262

Tech. info/Spec:

Market:

AU Mat. ID Code: PCC

File Name: 38413B.indd (CC - PC)

Replaces PCC: 38413A

Font Type: Helvetica World

Font Size: 9 pt

| x-height | Times New Roman compared to our standard fonts | | | | |
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| 1,104 mm | 7 pt xxx | 6 pt xxx | 5.1 pt xxx | 6.7 pt xxx | 7.2 pt xxx |
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| Yellow | 2. | | |
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