Patient Information Leaflet (PIL)

SCHEDULING STATUS
Schedule 4

TREMFYA® 100 mg solution for injection in pre-filled syringe and/or pre-filled pen

Guselkumab

Contains sugar (sucrose).

Each 1 mL of Tremfya 100 mg dose contains 79 mg sucrose.

Read all of this leaflet carefully before you start using TREMFYA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TREMFYA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TREMFYA is and what it is used for
2. What you need to know before you use TREMFYA
3. How to use TREMFYA
4. Possible side effects
5. How to store TREMFYA
6. Contents of the pack and other information

1. What TREMFYA is and what it is used for

TREMFYA contains the active substance guselkumab which is a type of protein called a monoclonal antibody. This medicine works neutralising the activity of a protein called IL-23, which is present at increased levels in people with psoriasis.

Plaque psoriasis

TREMFYA is used to treat adults with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin and nails.

TREMFYA can improve the skin clearance and nail appearance and reduce symptoms of psoriasis, such as scaling, shedding, flaking, itching, pain and burning. TREMFYA may improve your health-related quality of life.

Psoriatic arthritis

TREMFYA is used to treat adults with active psoriatic arthritis, an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given TREMFYA alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug (DMARD) such as methotrexate.

2. What you need to know before you use TREMFYA

Do not use TREMFYA

- if you are hypersensitive (allergic) to guselkumab or any of the other ingredients in TREMFYA (listed in section 6).
- if you have clinically important active infections, irrespective of the pathogen.
- if you have active tuberculosis.
- if you are pregnant or breastfeed your infant.
- You should not be given live vaccines while using TREMFYA.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using TREMFYA.

Infections

Before starting TREMFYA, tell your healthcare provider if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have tuberculosis (TB) or have been in close contact with someone with TB
- think you have an infection or have symptoms of an infection such as:
  - fever or flu like symptoms
  - blood in your phlegm (mucus)
  - muscle aches
  - weight loss
  - cough
  - diarrhoea or stomach pain
  - shortness of breath
  - warm, red, or painful skin or sores on your body different from psoriasis
  - burning when you urinate or urinating more often than normal.

After starting TREMFYA, call your healthcare provider right away if you have any of the symptoms of infection listed above.

TREMFYA may lower your ability to fight infections and may increase your risk of infections. Do not use TREMFYA if you have any symptoms of infection unless you are instructed to by your healthcare professional.

Vaccinations:

Tell your doctor if you have recently had a vaccination or if you are due to have a vaccination during treatment with TREMFYA.

You should not be given certain types of vaccines (live vaccines) while using TREMFYA.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using TREMFYA.

Allergic reactions

Serious allergic reactions, which can include symptoms of a swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, hives and shortness of breath, have occurred with TREMFYA. Tell your doctor or get emergency medical help right away if you think you are having an allergic reaction.

Children and adolescents

TREMFYA is not recommended for children and adolescents (younger than 18 years) because it has not been studied in this age group.

Other medicines and TREMFYA:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy and Breastfeeding:

You must not become pregnant while receiving TREMFYA or for 12 weeks after your last treatment.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using TREMFYA.

Contraception

If you are a woman of childbearing potential, use effective contraception while using TREMFYA and for at least 12 weeks after the last TREMFYA dose. Talk to your doctor about your contraception options.

Driving and using machines

It is not known if TREMFYA will affect the ability to drive or use machines.

TREMFYA contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using TREMFYA.

TREMFYA contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to use TREMFYA

Do not share medicines prescribed for you with any other person.

Always use TREMFYA exactly as your doctor has told you. Check with your doctor if you are not sure.

TREMFYA is given by injection under your skin (subcutaneous injection).

At the start of your therapy, TREMFYA may be injected by your healthcare provider. However, your healthcare provider may decide that it is right for you or your caregiver to learn how to inject TREMFYA under the skin (subcutaneously) yourself.

Before you self-inject TREMFYA, you must be trained by a healthcare professional. If you have not been trained, please contact your healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection.

Before use, remove the carton from the refrigerator and keep the pre-filled syringe or pre-filled pen inside the carton and allow to reach room temperature by waiting for 30 minutes. Read Refer to the "**Instructions for Use TREMFYA (Guselkumab) Prefilled Syringe and/or Prefilled Pen**" for the syringe carefully before using TREMFYA.

How much TREMFYA is given and for how long

Your doctor will decide how much TREMFYA you need and for how long.

Do not stop treatment early because your symptoms may return. If you have the impression that the effect of TREMFYA is too strong or too weak, tell your doctor or pharmacist.

For plaque psoriasis:

- The first dose is 100 mg (the content of 1 pre-filled syringe or pre-filled pen) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will have the next dose 4 weeks later, and then every 8 weeks. The following doses are the same as the first dose.

For psoriatic arthritis:

- The first dose is 100 mg (the content of 1 pre-filled syringe or pre-filled pen) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will have the next dose 4 weeks later, followed by a dose either every 8 weeks or every 4 weeks.

If you use more TREMFYA than you should

If you have received more TREMFYA than you should or the dose has been given sooner than prescribed, inform your doctor.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use TREMFYA

If you forget to inject your TREMFYA dose, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. Do not take a double dose to make up for forgotten individual doses. If you are not sure what to do, contact your doctor.

If you stop using TREMFYA

You should not stop using TREMFYA without speaking to your doctor first. If you stop treatment, your symptoms may come back.

4. Possible side effects

TREMFYA can cause side effects.

Not all side effects reported for TREMFYA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving TREMFYA, please contact your health care provider for advice.

Frequently reported side effects

- infections of the nose, sinuses or throat (common cold), chest infection
- stomach flu (gastroenteritis)
- fungal infection of the skin, for example between the toes (athlete's foot)
- herpes simplex infections, for example of the lips (cold sores) or genitals (genital herpes)
- headache
- diarrhoea
- joint pain
- redness, pain and irritation at the injection site
- allergic reaction
- skin rash
- hives
- decreased number of a type of white blood cell called neutrophils
- increased level of liver enzymes in the blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TREMFYA.

5. How to store TREMFYA

Store all medicine out of reach of children

If you are using TREMFYA at home, it is important to store the product in your refrigerator (2 ºC – 8 ºC) and not in the freezer compartment. TREMFYA should not be frozen. Keep the product in the original carton to protect from light until the time of use. Do not shake the product.

Do not use TREMFYA:

- After the expiry date, which is stated on the label and the carton after "EXP". The expiry date refers to the last day of that month;
- If the seal is broken;
- If the liquid is discoloured, cloudy or you can see other particulate matter floating in it.

How to Dispose of TREMFYA

- Used syringes and pens should be placed in a puncture-resistant container, like a sharps container.
- Return your full sharps container to your doctor or local pharmacy for destruction.
- Empty vials, antiseptic wipes, and other supplies can be placed in your regular trash.
- The pre-filled syringe and/or pre-filled pen, must never be re-used.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TREMFYA contains

- The active substance is guselkumab. Each pre-filled syringe or pre-filled pen contains 100 mg of guselkumab in 1 mL solution.
- The other ingredients are L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injections.
- Contains sugar (sucrose).

What TREMFYA looks like and contents of the pack

TREMFYA 100 mg solution for subcutaneous injection is a clear, colourless to light yellow solution and may contain clear or white particles of protein. This appearance is not unusual for solutions containing protein.

TREMFYA 100 mg solution for injection in pre-filled syringe

TREMFYA is supplied as a single-use sterile solution in a 1 mL Type I borosilicate glass syringe with a fixed 27G, half inch needle assembled in a clear, plastic passive needle guard delivery system - UltraSafe Plus™ Passive Delivery System (PFS-U). The PFS-U is placed in a light blue polyethylene terephthalate (PET) tray insert packed in an outer carton. The outer carton is made of paper board with white base colour. The components of the UltraSafe™ are presented in tabular format in Table 1. TREMFYA is available as a one pack only.

Table 1: Components of UltraSafe Plus™

Component Part	Material
Body	Medical grade polycarbonate (clear)
Needle guard	Medical grade polycarbonate (clear)

Spring	Type 302 Stainless steel spring wire
Plunger rod	Medical grade polypropylene (aqua/teal)

TREMFYA 100 mg solution for injection in pre-filled pen

1 mL solution in a pre-filled glass syringe assembled in a pre-filled pen with an automatic needle guard, packed in an outer carton. TREMFYA is available as a one pack only.

Holder of Certificate of Registration

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This leaflet was last revised in

6 March 2025

Registration number

52/30.1/0400

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.

Instructions for Use

TREMFYA (guselkumab) Prefilled Syringe



SINGLE-USE

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 prefilled syringe before attempting to inject.

Please read these **Instructions for Use** before using the 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 doctor 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 **2° to 8°C**. **Do not** freeze.

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

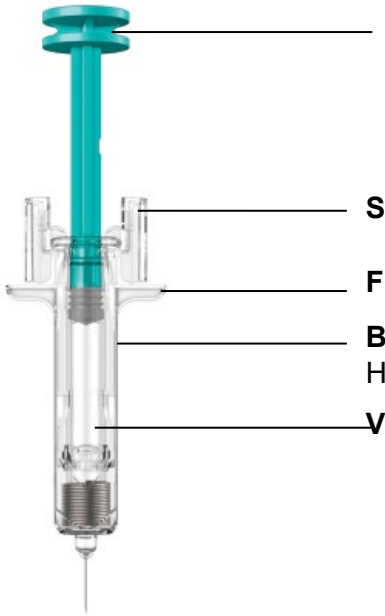
Do not shake the prefilled syringe at any time.

Need help?

Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback call JANSSEN on 0860 111 117.

Pre-filled safety syringe at-a-glance

Before injection



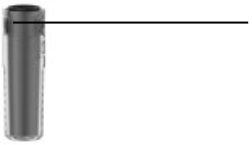
Plunger
Do not hold or pull plunger at any time.

Safety guard

Finger flange

Body
Hold syringe body **below** finger flange.

Viewing window



Needle cover
Do not remove until you are ready to inject TREMFYA (See Step 2).

After injection



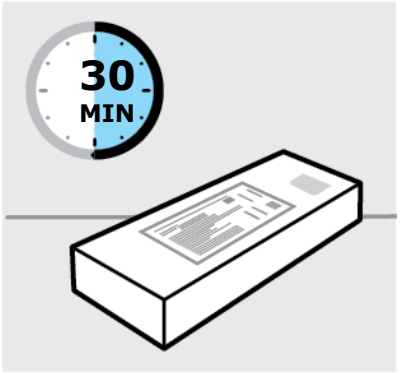
Plunger locks

Safety guard activates

Needle retracts into the body

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 prefilled syringe from the refrigerator.

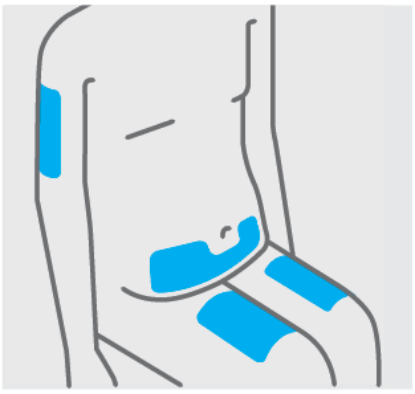
Keep the prefilled syringe in the carton and let it sit on a flat surface at room temperature for **at least 30 minutes** before use.

Do not warm 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 broken. Call your doctor or pharmacist for a refill.

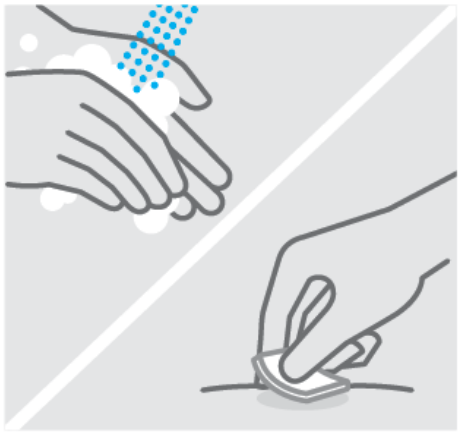


Choose injection site

Select from the following areas for your injection:

- **Front of thighs** (recommended)
- Lower abdomen (**do not** use the 5-centimeter area around your navel (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.

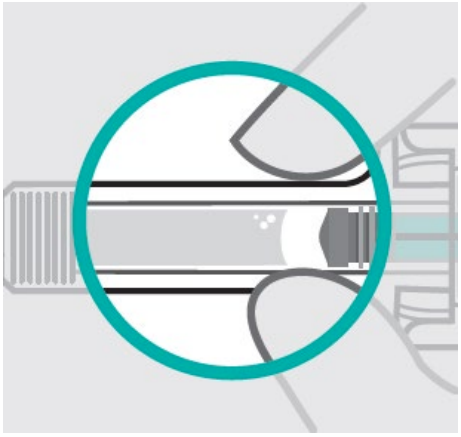


Clean injection site

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.



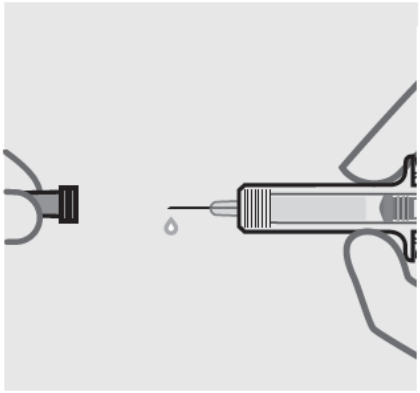
Inspect liquid

Take the prefilled 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.

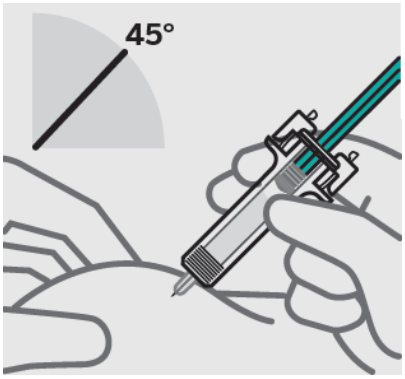
It is normal to see a drop of liquid.

Inject within 5 minutes of removing the needle 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 prefilled 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.

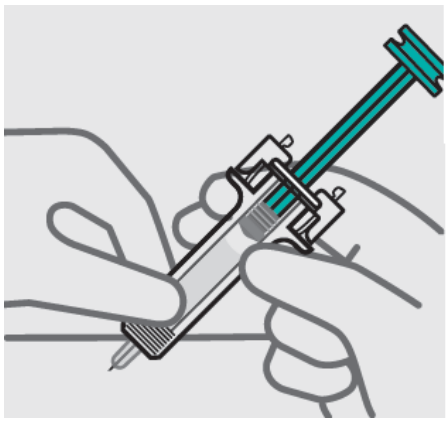
Do not touch plunger or area above finger flange as this may cause the needle safety device to activate.

Use your other hand to pinch skin at the injection site.

Position syringe at about a 45-degree angle to the skin.

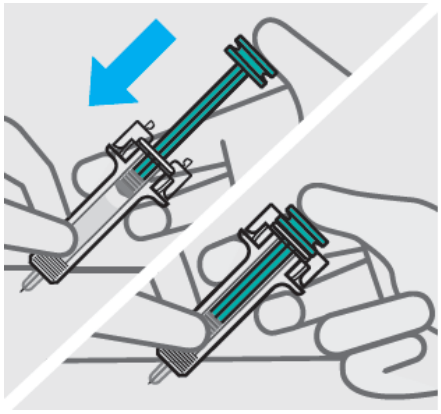
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



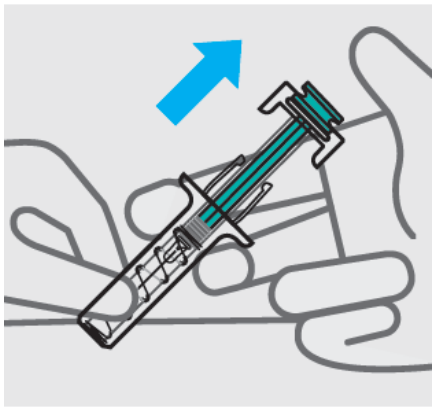
Release pinch and reposition hand

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



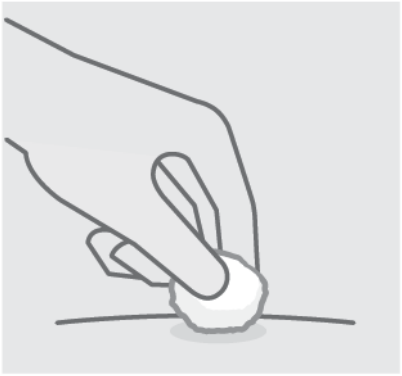
Dispose of your prefilled syringe

Put your used safety syringe in a BIOHAZARD-cleared sharps disposal container right away after use.

Do not throw away (dispose of) loose needles and syringes in your household trash.

Do not recycle your used sharps disposal container.

For more information, see "How to Dispose of TREMFYA"



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!

How should I dispose of the used prefilled syringe?

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

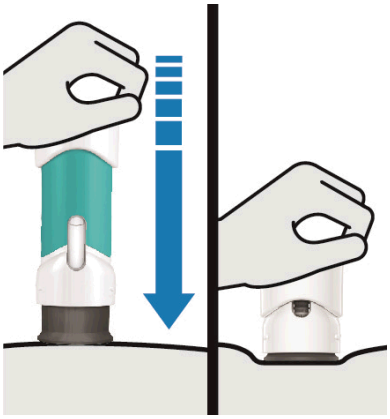
- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, please take it to your local pharmacy or doctor for disposal.

Instructions for use

TREMFYA

100 mg 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 Patient Information Leaflet carefully before starting your injection and discuss any questions you may have with your doctor or nurse.

During injection, push handle all the way down until teal body is not visible to inject the full dose.

DO NOT LIFT THE PRE-FILLED PEN during injection. If you do, the pre-filled pen will lock and you will not get the full dose.



Storage information

Store in refrigerator at 2° to 8°C.

Do not freeze.

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

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 call JANSSEN on 0860 111 117.

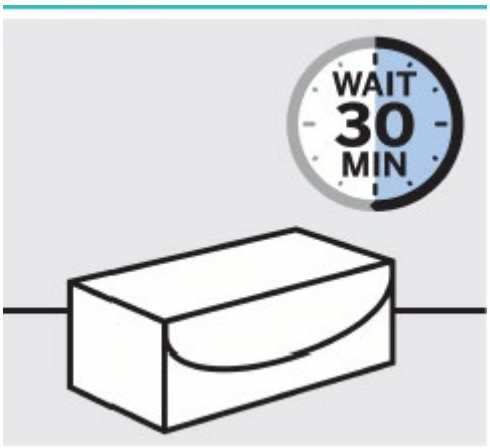
Pre-filled pen at-a-glance



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

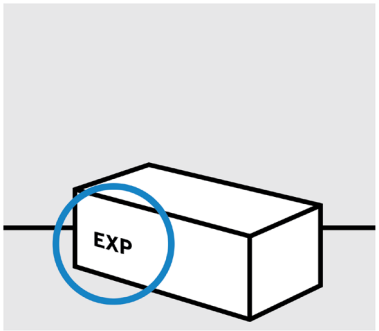


Inspect carton and allow Tremfya to come to room temperature.

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 approximately 30 minutes before use.

Do not warm any other way.



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

Do not use if the expiration date has passed.

Do not inject if the seal on the carton is broken.

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



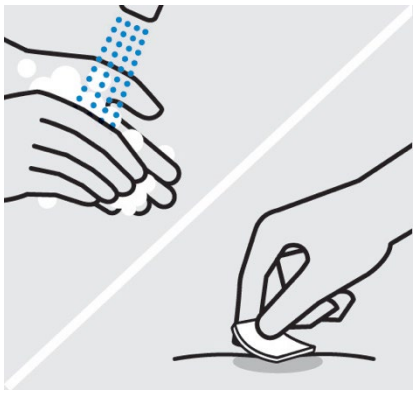
Choose injection site

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.



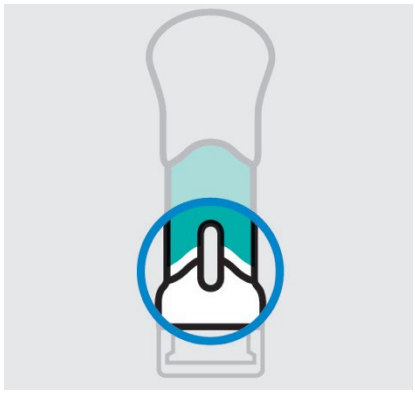
Wash hands

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.

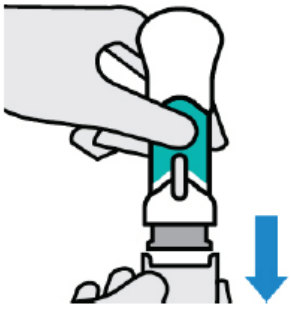
This is normal.

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



Pull off bottom cap when you are ready to inject. It is normal to see a few drops of liquid.

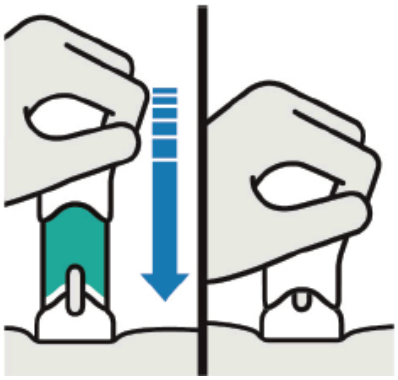
Keep hands away from the needle guard after the cap is removed.

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 straight on skin

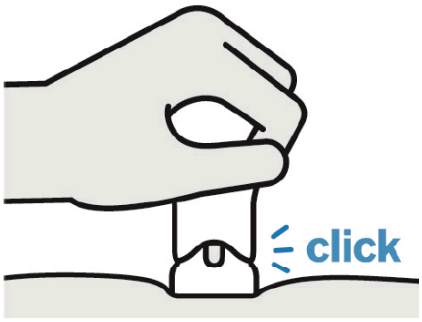
Push handle all the way down until teal body is not visible

DO NOT LIFT THE PRE-FILLED PEN DURING THE 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.

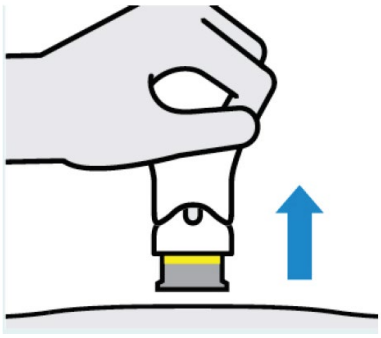
Do this at a speed that is comfortable for you.



Confirm injection is complete

Injection is complete when:

- The teal body is no longer 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



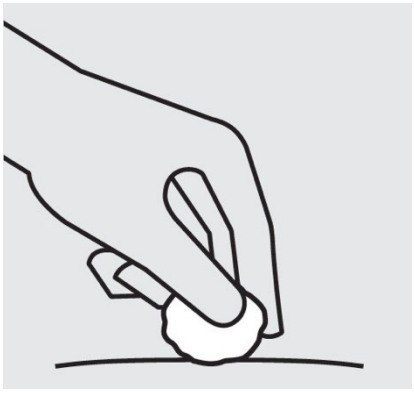
Throw the used pre-filled pen away

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.

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

Do not recycle your used sharps disposal container.



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!