



TREMFYA[®] (guselkumab)

Information for patients



Pre-filled syringe

■ Please read this booklet carefully as it contains important information about TREMFYA[®], the treatment that your doctor has prescribed to treat your psoriasis.

▼ This medicinal product is subject to additional monitoring.



What is Psoriasis?

Psoriasis often gets classified as 'just a skin condition'. However, this is simply not correct. To be more accurate, it's best to call it an autoimmune condition. This is because the cause of your psoriasis lies beneath your skin. What this means is that the part of your body

that defends you from infection and disease (your immune system) attacks your healthy skin cells by mistake. So your skin is affected by psoriasis, but the cause of your symptoms is a result of your immune system working too hard.

How TREMFYA® treats plaque psoriasis

TREMFYA® is a treatment indicated for adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy.

Psoriasis is an autoimmune condition. This means that your body's defense system (the immune system) is sending too many signals to your skin telling it to grow when it doesn't need to. That's why psoriasis skin can grow up to 10 times faster than non-psoriasis skin. TREMFYA®

works by stopping the signals from certain immune cells that tell skin to keep growing, bringing more of a balance to your immune system and a more even rate of skin growth.

The way TREMFYA® does this is by blocking a small protein in the body's cells called IL-23. By tightly binding to IL-23 TREMFYA® prevents the IL-23 protein from sending growth signals to your skin.

You can find a full list of side effects in your Package Leaflet.



How to use TREMFYA®

How does the treatment work?

TREMFYA® is administered as an injection under your skin (subcutaneous injection) with two starter

doses at weeks 0 and 4 and then every 8 weeks. The dose is 100 mg and comes in a pre-filled syringe.

Your doctor or nurse will inject TREMFYA® at the start of this treatment. However, you may decide together with your doctor to give TREMFYA® yourself. Your healthcare team can help you determine if self-injection is a good option for you. If you decide to self-inject, you will be trained by a nurse or other healthcare professional on the proper administration of TREMFYA®.

You can find full instructions for self-injection in the "Instructions for use" section in the Package Leaflet. Please note that you should not try to self-inject until you have received appropriate training from your doctor or nurse on how to inject TREMFYA®.



For more information please read "Instructions for use" from page 10



Considerations

Before you use TREMFYA® tell your doctor if you:

- ! If you are being treated for an infection
- ! If you have an infection that does not go away or that keeps coming back
- ! If you have tuberculosis or have been in close contact with someone with tuberculosis
- ! TREMFYA® may lower your ability to fight infections and may therefore increase your risk of infections and allergic reactions. Tell your doctor or seek medical help immediately if you notice any signs of an infection or an allergic reaction while you are taking TREMFYA®.



Frequently asked questions



Can other medicines /vaccines be taken with TREMFYA®?

Tell your doctor or pharmacist:



- If you are taking, have recently taken or might take any other medicines.
- If you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using TREMFYA®.



What if I'm trying to get pregnant?



The effects of TREMFYA® during pregnancy have not been studied, so it is not clear if it causes birth defects. If you are pregnant or are considering having a child you should discuss this with your doctor before starting this medication. Women in fertile age should use efficient contraceptives for 15 weeks after stopping treatment.



Can I breastfeed my baby if I am taking TREMFYA®?



TREMFYA® is likely to be excreted in the breastmilk of lactating women. Women who are breastfeeding should talk to their doctor about whether or not to use TREMFYA® during the time of breast feeding.

**What do I do if I miss a dose of TREMFYA®?**

If you forget or miss the appointment for being given the TREMFYA® dose, contact your doctor to reschedule your appointment. If you give yourself the injections and forget a dose, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

**How do I store TREMFYA®?**

You must store TREMFYA® in the following ways: Keep TREMFYA® out of the sight and reach of children. Keep your syringes or vials in a fridge (2–8°C). Do not keep them in the freezer. Keep the pre-filled syringes or vials in the outer carton to protect them from light. Do not shake the pre-filled syringes or vials as this may damage the medicine. Remove your treatment from the fridge 30 minutes before your injection so it can reach room temperature. If you think you've left your medicine out of the fridge longer than you should, place the vial or pre-filled syringe back in the fridge and contact your healthcare professional as soon as possible for advice.

**How do I dispose of my used TREMFYA® syringe?**

Used syringes should be placed in a puncture-resistant container, like a sharps container. Never re-use a syringe, for your safety and health and for the safety of others. Dispose of your sharps container according to your local regulations. Antiseptic wipes and other supplies can be disposed of in your garbage. Ask your pharmacist or doctor on how to dispose of medicines if you are unsure.

**What do I need to check before taking my injection?**

Before you use TREMFYA®, you should check that:

- It hasn't passed its expiry date. You can find the expiry date on the label and the carton after "Exp. Date/EXP". The expiry date refers to the last day of that month. Do not use TREMFYA® if the expiry date has passed.
- The medicine hasn't been exposed to extreme temperatures. Do not use TREMFYA® if you know, or think, that it may have been accidentally frozen or heated.
- The medicine hasn't been shaken vigorously. If it has been shaken, do not use it. Check that its appearance is intact. TREMFYA® is a clear to slightly opalescent (having a pearl-like shine), colourless to light yellow solution for injection. The solution may contain a few small translucent or white particles of protein. Do not use the medicine if the liquid is discoloured, cloudy or you can see other foreign particles in it.

**What if I use more TREMFYA® than recommended?**

If you think you have used more TREMFYA® than you should have, talk to a doctor or pharmacist straight away. If you can, take the outer carton of the medicine with you, even if it's empty.

**Can I stop using TREMFYA®?**

If you would like to stop taking TREMFYA® you should discuss this with your doctor first. He/she will advise you on the best way to do this. If you stop taking it, your symptoms may come back. If you have any questions on the use of this medicine, ask your doctor or pharmacist.

**Where can I get additional information on TREMFYA®?**

If you have a question about your treatment, please read the Package Leaflet and speak to your healthcare professional. For further information please contact Janssen Department of Medical Information, MICS (Medical Information and Customer Services).

Would you like more information?
Please contact Medical Information

020 7531 300 jacfi@its.jnj.com 045 7395 0730



Are there any **side effects** with TREMFYA®?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects are all mild to moderate.

Very common (may affect more than 1 in 10 people):

- Upper respiratory infections

Common (may affect up to 1 in 10 people):

- Headache
- Joint pain (arthralgia)
- Diarrhoea
- Stomach flu (gastroenteritis)
- Redness at the injection site
- Hives
- Fungal infection of the skin, for instance between the toes (e.g., athlete's foot)
- Herpes simplex infections

If any of these side effects becomes severe, tell your doctor, pharmacists or nurse immediately.

You can find a full list of side effects in your Package Leaflet. If you have any questions or concerns about your treatment, it's important that you speak with your nurse or doctor.



Instructions for use

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.

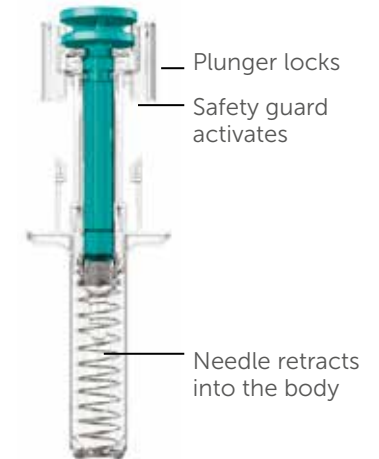
The TREMFYA® pre-filled syringe is intended for injection under the skin, not into the muscle or vein. After injection, the needle will retract into the body of the device and lock into place.

Pre-filled syringe at-a-glance

Before injection



After injection

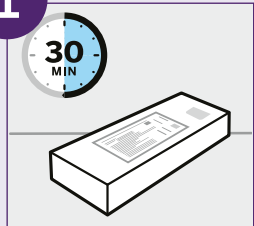


You will need these supplies:

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

1. Prepare for your injection

1



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.

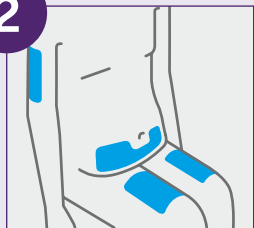
Do not warm any other way.

Check the 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.

2



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.

3



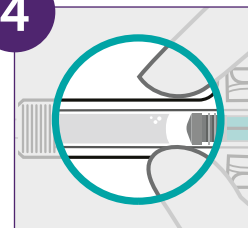
Clean injection site

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.

4



Inspect liquid

Take the pre-filled syringe out of the carton.

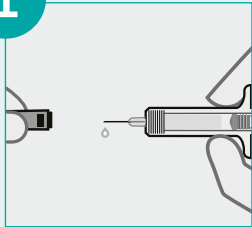
Check the liquid in the viewing window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see one or more air bubbles.

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

1



Remove needle cover

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

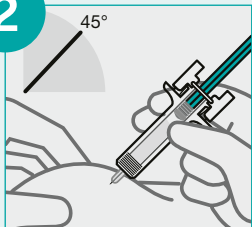
Inject within 5 minutes of removing the needle cover.

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.

2



Position fingers and insert needle

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

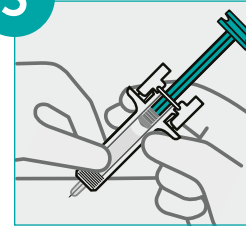
Do not touch plunger or area above finger flange as this may cause the needle safety device to activate.

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.

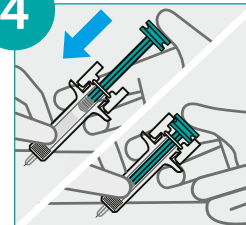
3



Release pinch and reposition hand

Use your free hand to grasp the body of the syringe.

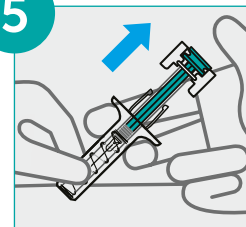
4



Press plunger

Place thumb from the opposite hand on the plunger and press the plunger **all the way down until it stops**.

5



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

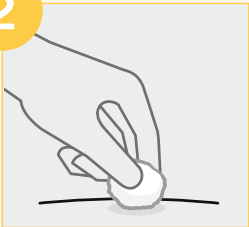
1



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.

2



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.



Reporting of side effects


If you get any side effects, talk to your doctor, nurse or pharmacist. This includes possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.




Injection calendar

2020			
APRIL 2020	MARCH 2020	FEBRUARY 2020	JANUARY 2020
AUGUST 2020	JULY 2020	JUNE 2020	MAY 2020
DECEMBER 2020	NOVEMBER 2020	OCTOBER 2020	SEPTEMBER 2020
APRIL 2020	MARCH 2020	FEBRUARY 2020	JANUARY 2020
AUGUST 2020	JULY 2020	JUNE 2020	MAY 2020
DECEMBER 2020	NOVEMBER 2020	OCTOBER 2020	SEPTEMBER 2020
2019			
APRIL 2019	MARCH 2019	FEBRUARY 2019	JANUARY 2019
AUGUST 2019	JULY 2019	JUNE 2019	MAY 2019
DECEMBER 2019	NOVEMBER 2019	OCTOBER 2019	SEPTEMBER 2019

Would you like more information?
Please contact Medical Information

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 jacfi@its.jnj.com

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