

Package leaflet: Information for the user

Tremfya 100 mg solution for injection in pre-filled pen guselkumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 by blocking the activity of a protein called IL-23, which is present at increased levels in people with psoriasis and psoriatic arthritis.

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 condition of the skin and appearance of nails and reduce symptoms, such as scaling, shedding, flaking, itching, pain and burning.

Psoriatic arthritis

Tremfya is used to treat a condition called “psoriatic arthritis”, an inflammatory disease of the joints, often accompanied by plaque psoriasis. If you have psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines or in case of intolerance, you will be given Tremfya to reduce the signs and symptoms of the disease. Tremfya can be used alone or with another medicine named methotrexate.

Using Tremfya in psoriatic arthritis will benefit you by reducing the signs and symptoms of the disease, slowing down the damage to the cartilage and bone of the joints and improving your ability to do normal daily activities.

2. What you need to know before you use Tremfya

Do not use Tremfya

- if you are allergic to guselkumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using Tremfya.
- if you have an active infection, including active tuberculosis.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tremfya:

- 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;
- if you think you have an infection or have symptoms of an infection (see below under ‘Look out for infections and allergic reactions’);
- if you have recently had a vaccination or if you are due to have a vaccination during treatment with Tremfya.

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

As directed by your doctor, you may need blood tests to check if you have high levels of liver enzymes before you start taking Tremfya and when using it. Increases in liver enzymes may occur more frequently in patients receiving Tremfya every 4 weeks than in patients receiving Tremfya every 8 weeks (see “How to use Tremfya” in section 3).

Look out for infections and allergic reactions

Tremfya can potentially cause serious side effects, including allergic reactions and infections. You must look out for signs of these conditions while you are taking Tremfya.

Signs of infections may include fever or flu like symptoms; muscle aches; cough; shortness of breath; burning when you urinate or urinating more often than usual; blood in your phlegm (mucus); weight loss; diarrhoea or stomach pain; warm, red, or painful skin or sores on your body which are different from your psoriasis.

Serious allergic reactions, which can include the following symptoms, swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing and hives, have occurred with Tremfya (see “Serious side effects” in section 4).

Stop using Tremfya and tell your doctor or seek medical help **immediately** if you notice any signs indicating a possible serious allergic reaction or an infection.

Children and adolescents

Tremfya is not recommended for children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and Tremfya

Tell your doctor or pharmacist:

- if you are using, have recently used or might use any other medicines.
- if you recently had or are due to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using Tremfya.

Pregnancy and breast-feeding

- Tremfya should not be used in pregnancy as the effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Tremfya and for at least 12 weeks after the last Tremfya dose. Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

- Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you will breast-feed or use Tremfya.

Driving and using machines

Tremfya is unlikely to influence your ability to drive and use machines.

3. How to use Tremfya

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much Tremfya is given and for how long

Your doctor will decide for how long you need to use Tremfya.

Plaque psoriasis

- The dose is 100 mg (the content of 1 pre-filled pen) given by injection under the skin (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.

Psoriatic arthritis

- The dose is 100 mg (the content of 1 pre-filled pen) given by injection under the skin (subcutaneous injection). This may be given by your doctor or nurse.
- After the first dose, you will receive the next dose 4 weeks later, and then every 8 weeks. For some patients, after the first dose, Tremfya may be given every 4 weeks. Your doctor will decide how often you may receive Tremfya.

At the start, your doctor or nurse will inject Tremfya. However, you may decide together with your doctor to give Tremfya yourself in which case you will get the appropriate training on how to inject Tremfya. Talk to your doctor or nurse if you have any questions about giving yourself an injection. It is important not to try to inject yourself until you have been trained by your doctor or nurse.

For detailed instructions on how to use Tremfya, carefully read the 'Instructions for use' leaflet before use, which is included in the carton.

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.

If you forget to use Tremfya

If you have forgotten to inject a dose of Tremfya, inform 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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor or seek medical help immediately if you get any of the following side effects:

Possible serious allergic reaction (may affect up to 1 in 100 people) - the signs may include:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Other side effects

The following side effects are all mild to moderate. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse immediately.

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

- respiratory tract infections

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

- headache
- joint pain (arthralgia)
- diarrhoea
- redness, irritation or pain at the injection site
- increased level of liver enzymes in the blood

Uncommon (may affect up to 1 in 100 people):

- allergic reaction
- skin rash
- decreased number of a type of white blood cell called neutrophils
- herpes simplex infections
- fungal infection of the skin, for instance between the toes (e.g., athlete's foot)
- stomach flu (gastroenteritis)
- hives

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tremfya

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pre-filled pen label and on the outer carton after "EXP". The expiry date refers to the last day of that month.

Keep the pre-filled pen in the outer carton in order to protect from light.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Do not shake.

Do not use this medicine if you notice that the medicine is cloudy or discoloured, or contains large particles. Before use, remove the carton from the refrigerator and keep the pre-filled pen inside the carton and allow to reach room temperature by waiting for 30 minutes.

This medicine is for single use only. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tremfya contains

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

What Tremfya looks like and contents of the pack

Tremfya is a clear, colourless to light yellow solution for injection (injection). It is available in packs containing one pre-filled pen and in multipacks comprising 2 cartons, each containing 1 pre-filled pen. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Janssen-Cilag Ltd
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

Manufacturer

Janssen Biologics B.V.
Einsteinweg 101
2333CB Leiden
The Netherlands

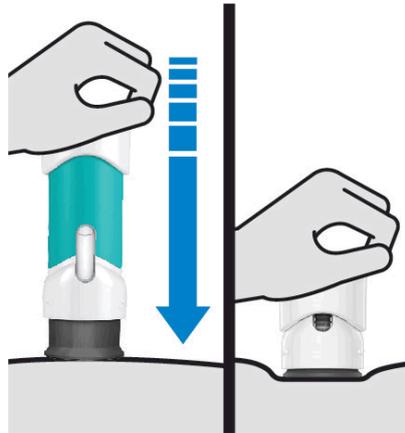
For information in large print, tape, CD or Braille, telephone 0800 7318450

This leaflet was last revised in October 2024

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 Package 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 green 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.

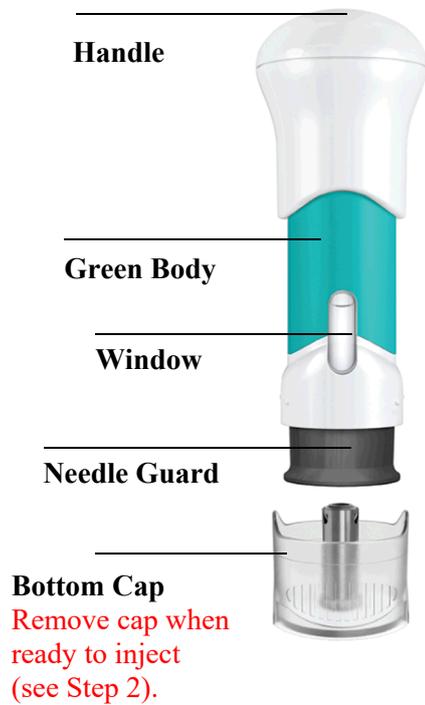


Need help?

Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback refer to the Package Leaflet for your local representative contact information.

Pre-filled pen at-a-glance

Before use



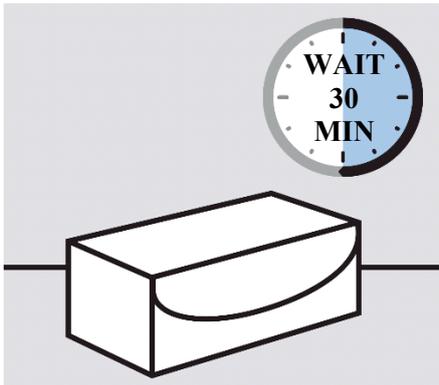
After use



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

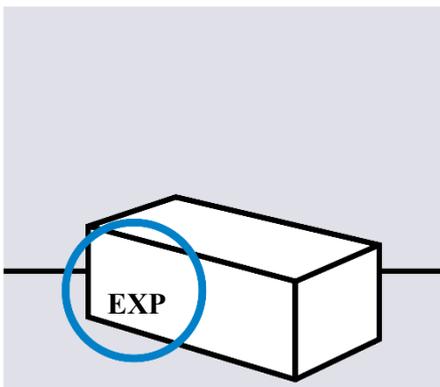


Inspect carton and allow Tremfya to come to room temperature

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 **approximately 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 the seal on the carton is broken.

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

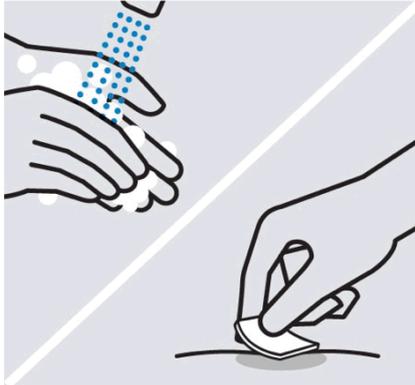


Choose injection site

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.



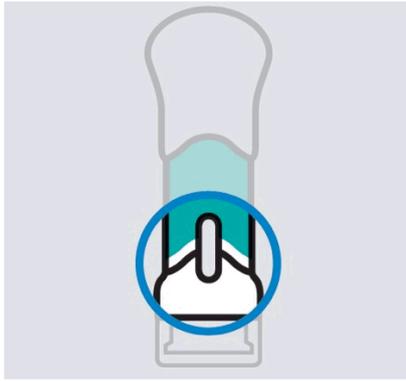
Wash hands

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.

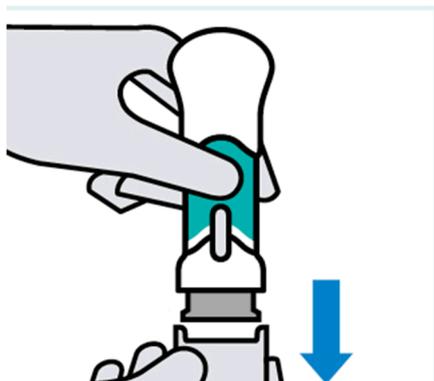
This is normal.

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



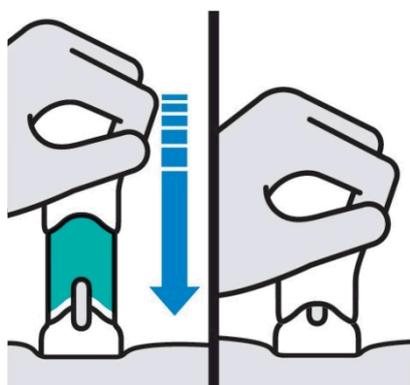
Pull off bottom cap when you are ready to inject

Keep hands away from the needle guard after the cap is removed. It is normal to see a few drops of liquid.

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 green body is not visible

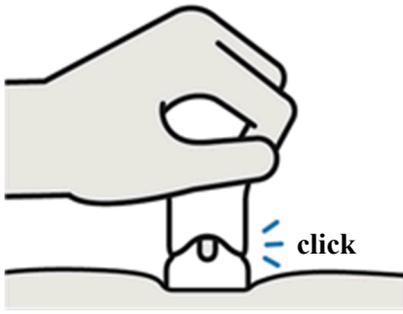
DO NOT LIFT THE PRE-FILLED PEN DURING THE INJECTION!

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.

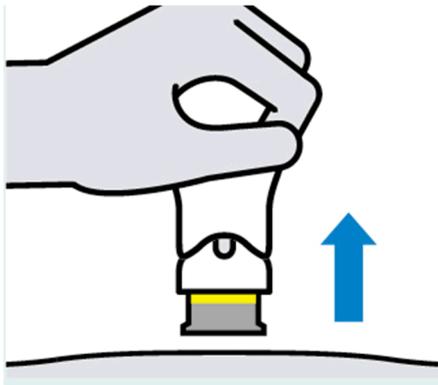
The medication injects as you push. Do this at a speed that is comfortable for you.



Confirm injection is complete

Injection is complete when:

- **The green 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



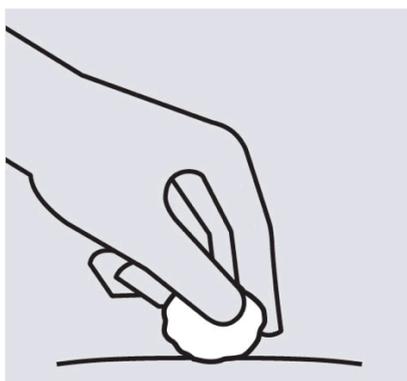
Throw the used pre-filled pen away

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!