

Package leaflet: Information for the user

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

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. This leaflet has been written for the person taking the medicine. If you are the parent or caregiver who will give Tremfya to a child, please read this information carefully.

- 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.

Plaque psoriasis in children

Tremfya is used to treat children 6 years of age and older with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin.

Tremfya can improve the condition of the skin and reduce signs and symptoms, such as scaling and redness.

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. Children need to be brought up to date with age-appropriate vaccines prior to beginning Tremfya.

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

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 or symptoms 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 have occurred with Tremfya. Symptoms may include 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 under 6 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.

Tremfya contains polysorbate 80

This medicine contains 0.3 mg of polysorbate 80 in each dosage unit which is equivalent to 0.5 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

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 in children from the age of 6 years

- For children weighing 40 kg or more, the dose is 100 mg (the content of 1 pre-filled syringe) given by injection under the skin (subcutaneous injection). This may be given by your doctor or nurse.
- For children weighing less than 40 kg, a 45 mg/0.45 mL pre-filled pen is available.
- After the first dose, you will have the next dose 4 weeks later, and then every 8 weeks.

At the start, your doctor or nurse will inject Tremfya. Your doctor may decide that your caregiver may be able to give Tremfya after receiving appropriate training from your doctor on how to inject Tremfya. Talk to your doctor or nurse if you have any questions about your injection

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

Stop using Tremfya, 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 1000 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
- lightheadedness, low blood pressure or dizziness

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
- skin rash

Uncommon (may affect up to 1 in 100 people)

- 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

Rare (may affect up to 1 in 1,000 people)

- allergic reaction

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 syringe label and on the outer carton after "EXP". The expiry date refers to the last day of that month.

Keep the pre-filled syringe 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 syringe 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 syringe contains 100 mg of guselkumab in 1 mL solution.
- The other ingredients are histidine, histidine monohydrochloride monohydrate, polysorbate 80 (E433), 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 syringe and in multipacks comprising 2 cartons, each containing 1 pre-filled syringe. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

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

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**Instructions for use
Tremfya
100 mg pre-filled syringe**



SINGLE-USE DEVICE

Important

If your doctor decides that a caregiver may be able to give your injections of Tremfya at home, **they should receive training on the correct way to prepare and inject Tremfya using the pre-filled syringe before attempting to inject**. If your caregiver has not been trained, or has any questions, please call your doctor.

Please read these Instructions for use before using the Tremfya pre-filled syringe and each time you get a new pre-filled syringe. 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 the 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°C 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.

Keep the pre-filled syringe in the original carton to protect from light and physical damage.

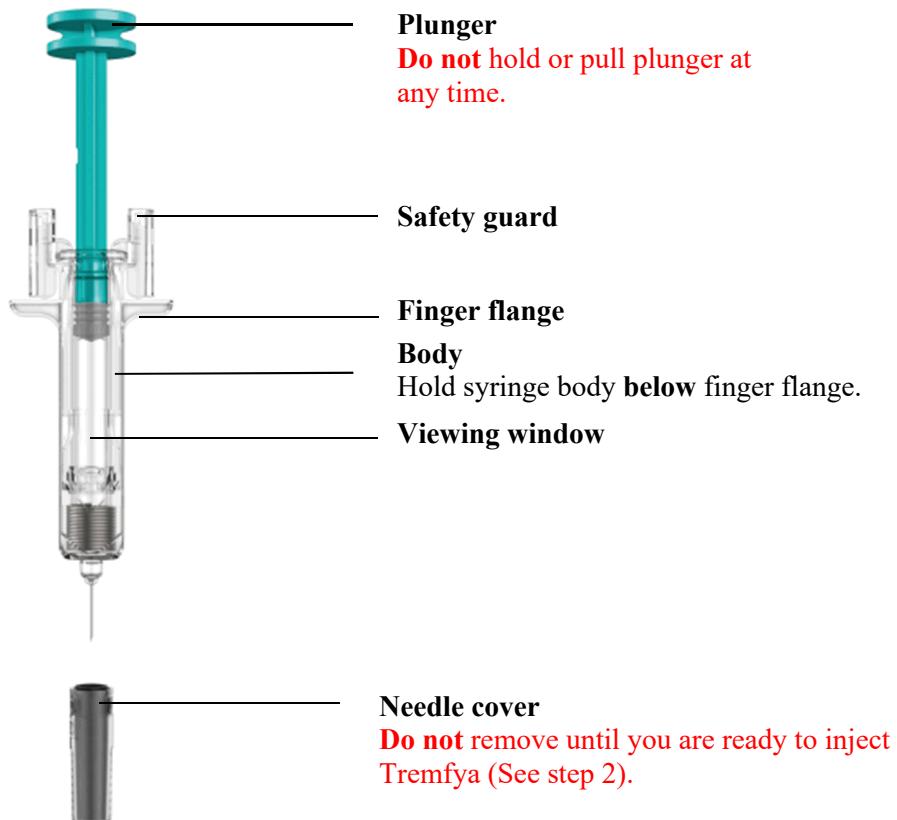


Need help?

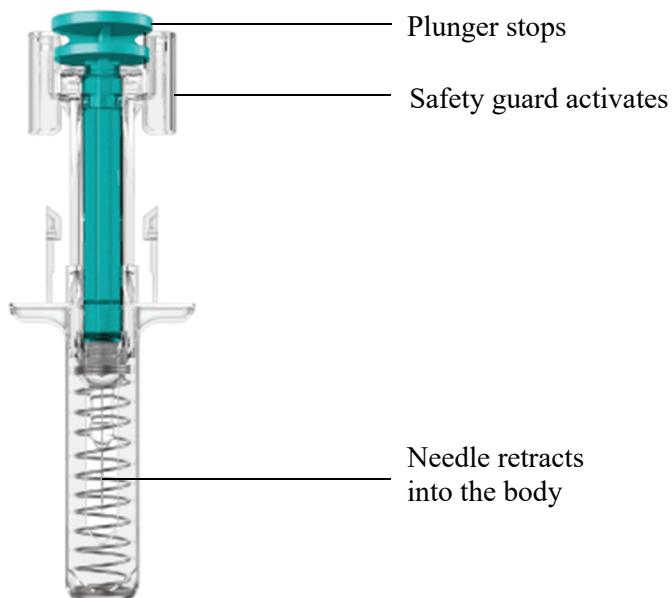
Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback refer to the Package Leaflet for your local representative contact information.

Pre-filled syringe at-a-glance

Before injection



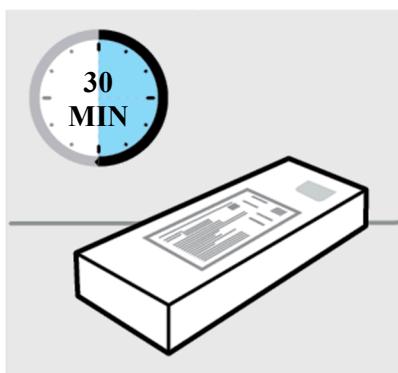
After injection



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.

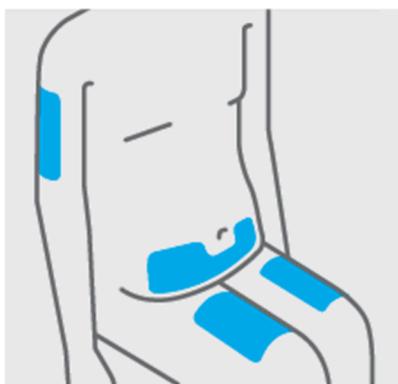
Do not warm any other way.

Check the expiry date ('EXP') on the back panel of the carton.

Do not use if the expiry date has passed.

Do not inject if the perforations on the carton are broken.

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



Choose injection site

Select from the following areas for your injection:

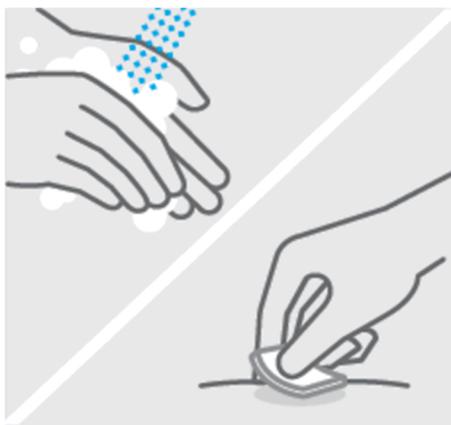
- Front of thighs (recommended)
- Lower abdomen

Do not use the 5-centimetre area around your belly-button.

- Back of upper arms

Do not inject into skin that is tender, bruised, red, scaly or hard.

Do not inject into areas with scars or stretch marks.

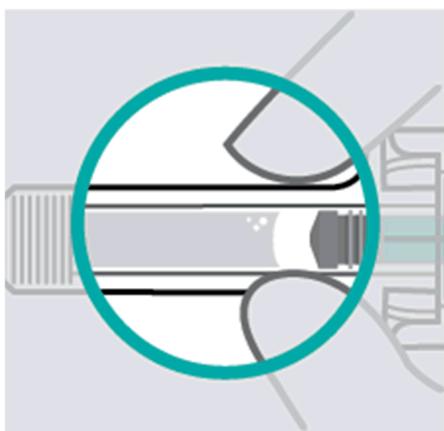


Clean injection site

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

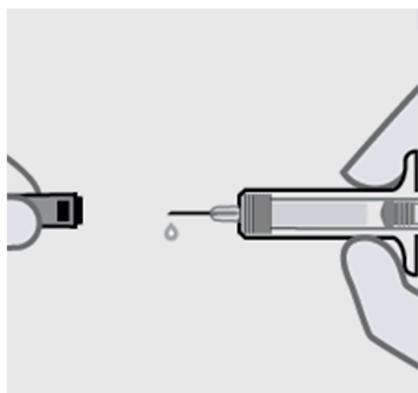
Take the pre-filled syringe out of the carton.

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 new pre-filled syringe.

2. Inject Tremfya using the pre-filled syringe



Remove needle cover

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

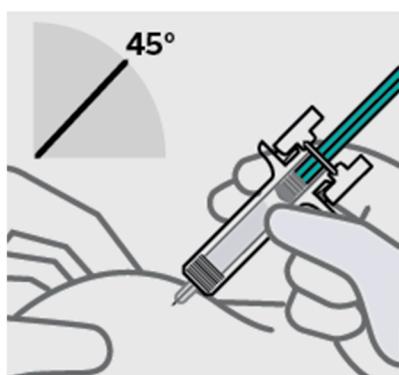
It is normal to see a drop of liquid.

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 new pre-filled syringe.



Position fingers and insert needle

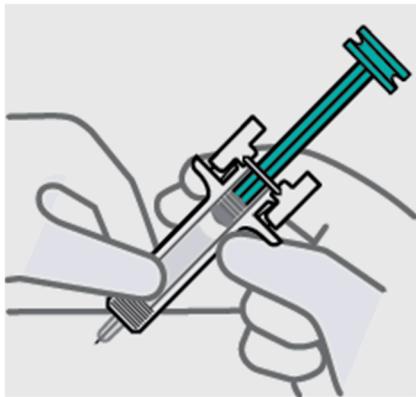
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

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.

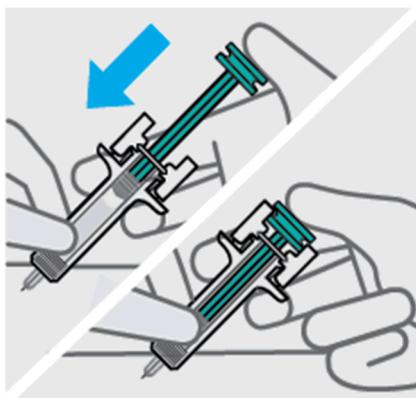
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



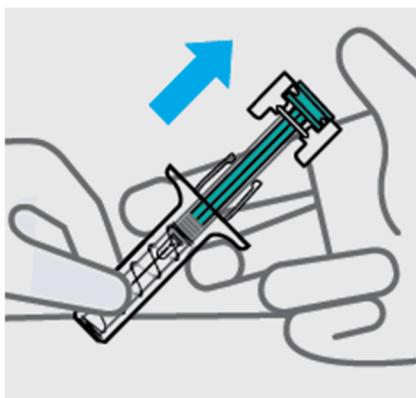
Release pinch and reposition hand

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 to remove needle from the skin

The needle will retract into the device and lock into place.

3. After your injection

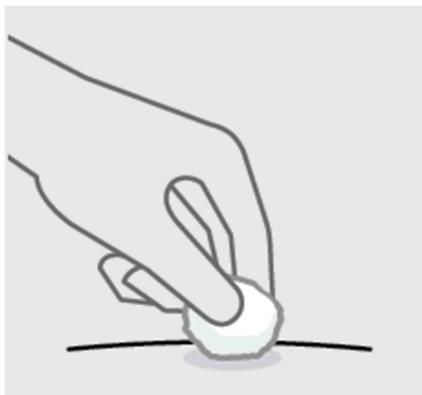


Throw the used pre-filled syringe away

Put your used syringe in a sharps disposal container right away after use.

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

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!