

Package leaflet: Information for the user

Tremfya® 200 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.

- 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 Crohn's disease and ulcerative colitis.

Crohn's disease

Tremfya is used to treat adults with moderate to severe Crohn's disease, an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Tremfya.

Using Tremfya in Crohn's disease can benefit you by reducing the signs and symptoms of the disease such as diarrhoea, abdominal pain, and the inflammation of your intestinal lining. These effects can improve your ability to do normal daily activities and reduce fatigue.

Ulcerative colitis

Tremfya is used to treat adults with moderate to severe ulcerative colitis, an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Tremfya.

Using Tremfya in ulcerative colitis can benefit you by reducing the signs and symptoms of the disease including bloody stools; the need to rush to and the number of times you go to the toilet, abdominal pain and the inflammation of your intestinal lining. These effects can improve your ability to do normal daily activities and reduce fatigue.

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 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 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, lightheadedness or dizziness, or hives (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

- **Pregnancy** 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 1 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.

Crohn's disease

- **Treatment start** can be given either by intravenous infusion or administered subcutaneously. Intravenous infusion: The first dose of Tremfya is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm). After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.
- Subcutaneous administration: The first dose of Tremfya is 400 mg and will be under the skin (subcutaneous injection) at different locations of the body. After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.

Maintenance therapy: A maintenance dose of Tremfya will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive.

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose and then every 4 weeks.

Ulcerative Colitis

Treatment start:

- Intraavenous infusion: The first dose of Tremfya is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm). After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.
- Subcutaneous administration: The first dose of Tremfya is 400 mg and will be given under the skin (subcutaneous injection) at different locations of the body. After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.

Maintenance therapy: A maintenance dose of Tremfya will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive.

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose and then every 4 weeks.

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

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 or symptoms 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

- increased level of liver enzymes in the blood
- skin rash
- redness, irritation or pain at the injection site

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 200 mg of guselkumab in 2 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 Ltd
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

Manufacturer

Janssen Biologics B.V.
Ernstennweg 101
2333CB Londen
The Netherlands

This leaflet was last revised in 12/2025



GB - MU_123542197



GB - MU_123542197

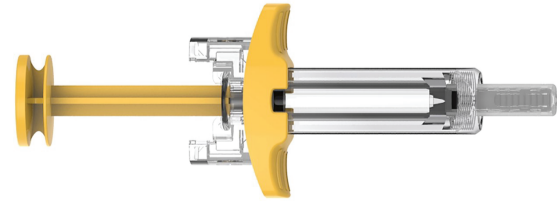


GB - MU_123542197



GB - MU_123542197

Instructions for use Tremfya® 200 mg Pre-filled Syringe



SINGLE-USE

Important

Tremfya comes in a single-use pre-filled syringe containing one 200 mg dose.

Your doctor will tell you if you will need to use 1 or 2 pre-filled syringes.

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.

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.

Each Tremfya pre-filled syringe can only be used one time. Throw the used pre-filled syringe away (see Step 4) after one dose, even if there is still medicine left in it. Do not reuse your Tremfya pre-filled syringe. 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 device and lock into place.

Storage information

Store in refrigerator at 2° to 8°C.
Do not freeze.
Do not shake your pre-filled syringe.

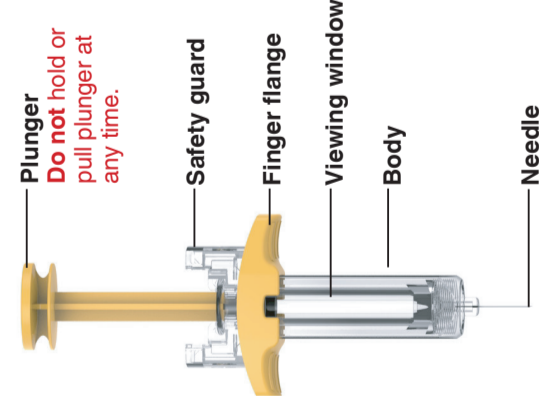
Keep your pre-filled syringe in the original carton to protect from light and physical damage. Keep Tremfya and all medicines out of reach of children.

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 syringe at-a-glance

Before use



Plunger
Do not hold or pull plunger at any time.

Safety guard

Finger flange

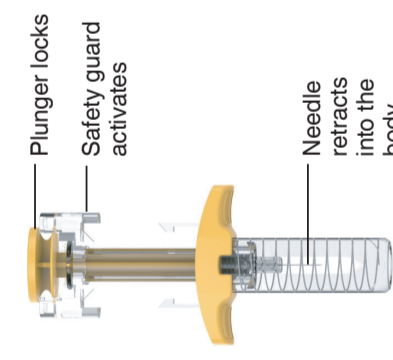
Viewing window

Body

Needle

Needle cover
Do not remove until you are ready to inject (See Step 3)

After use



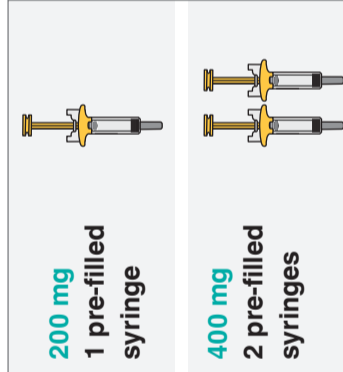
Plunger locks
Safety guard activates

Needle
retracts into the body

You will need:
based on the dose prescribed by your doctor
the carton:

- 1 or 2 pre-filled syringes and 2 pre-filled syringes and inspect carton(s)
- Alcohol swabs
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps container (See Step 4)

1. Get ready



200 mg
1 pre-filled syringe

400 mg
2 pre-filled syringes

Check your dose to see if you will need to use 1 or 2 pre-filled syringes and inspect carton(s)

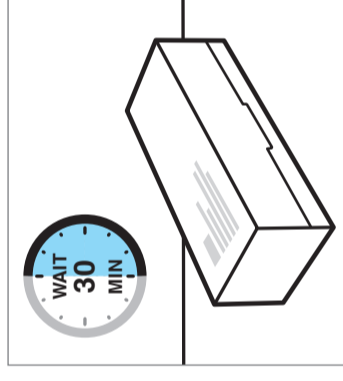
Remove the carton(s) with the pre-filled syringe from the refrigerator.

Check the expiry ("EXP") date.
Do not use the pre-filled syringe if the expiry date has passed or if the seal on the carton is broken. Call your doctor or pharmacist for a new pre-filled syringe.

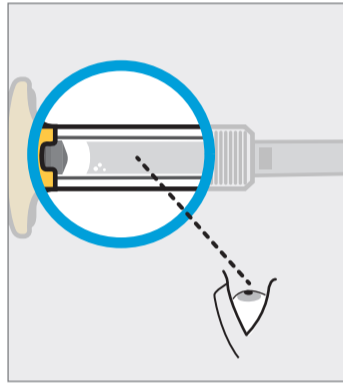
Allow Tremfya to come to room temperature

Let the carton(s) sit on a flat surface at room temperature for approximately 30 minutes before use.

Do not warm the pre-filled syringe(s) any other way.



2. Prepare for your injection



Inspect liquid to see that it is clear to slightly yellow

Take the pre-filled syringe out of the carton.

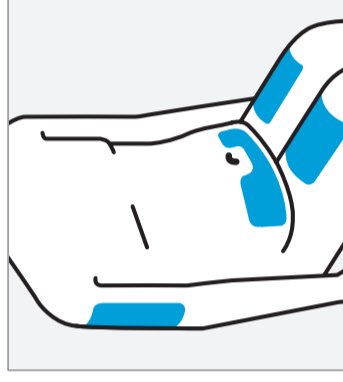
Check the liquid in the viewing window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see air bubbles. This is normal.

Do not inject if the liquid is:

- cloudy or
- has large particles

Do not use the pre-filled syringe if it is dropped.

If you are uncertain, call your doctor or pharmacist for a new pre-filled syringe.



Choose injection site

Select a site from the following areas for your injection:

- Front of thighs
 - Lower stomach area (lower abdomen)
- Do not** use the 5-centimetre area around your belly-button
- Back or upper arms (if a caregiver is giving you the injection)

If you need to give 2 injections to complete your dose, choose different areas or leave at least 5-centimetres between injection sites.

Do not inject into skin that is tender, bruised, red, scaly, thick or hard. Avoid areas with scars or stretch marks.

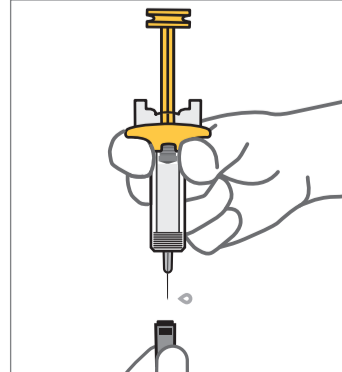


Wash hands and clean injection site

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.

3. Inject Tremfya using the pre-filled syringe



Remove needle cover when you are ready to inject

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

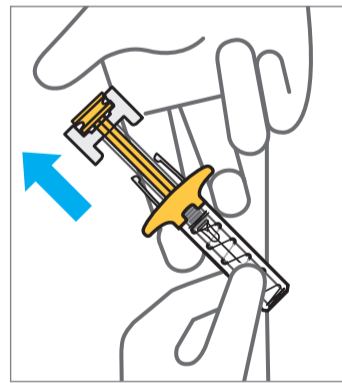
It is normal to see a few drops of liquid.

Inject Tremfya within 5 minutes of removing the needle cover.

Do not put needle cover back on, as this may damage the needle or cause a needle stick injury. **Do not** touch needle or let it touch any surface.

Do not use the pre-filled syringe if it is dropped. Call your doctor or pharmacist for a new pre-filled syringe.

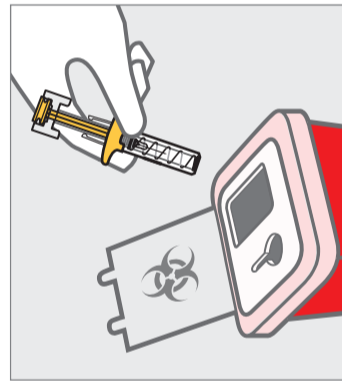
Do not hold or pull the plunger at any time.



Release pressure from plunger to remove the needle from the skin

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

If your prescribed dose requires two injections, repeat Steps 2 to 4 with the second pre-filled syringe.



Check injection site

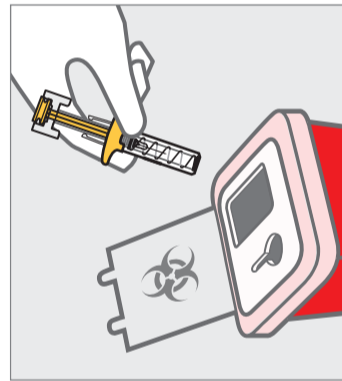
There may be a small amount of blood or liquid at the injection site.

Gently hold pressure over the injection site with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site. If needed, cover the injection site with a bandage.

Your injection is now complete!

4. After your injection



Throw away the used pre-filled syringe

Put the used pre-filled 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.

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

Do not recycle your used sharps disposal container.

AUTOMATED LEGEND (CC-PC)

Product Artwork

Latest Modification Date: December 12, 2025 01:09 PM

Artwork Operator: V_PS

Version: 1

IFU-Insert TREMFYA

PCC MU_123542197

Template Ref. Name: Schaffhausen/IFU-Insert/2905/2

Template Dimensions: 700 x 398

Tech. info/Spec:

Market: GB

Mat. ID Code: PCC (123542197)

File Name: MU_123542197.indd

Replaces PCC:

Font Type: Helvetica World

Font Size: 9 pt

x-height (lowercase) Times NR	Times New Roman compared to our standard fonts						
	Times New Roman	Helvetica World	Antique Olive	Futura	Karlon	Univers Next W1G	Johnson text
0,917 mm	6 pt xxx	5,2 pt xxx	4,1 pt xxx	5,8 pt xxx	6,2 pt xxx	5,3 pt xxx	5,3 pt xxx
1,104 mm	7 pt xxx	6 pt xxx	5,1 pt xxx	6,7 pt xxx	7,2 pt xxx	6,2 pt xxx	6,2 pt xxx
1,262 mm	8 pt xxx	6,9 pt xxx	5,8 pt xxx	7,7 pt xxx	8,2 pt xxx	7,1 pt xxx	7,1 pt xxx
1,42 mm	9 pt xxx	7,7 pt xxx	6,5 pt xxx	8,6 pt xxx	9,2 pt xxx	8 pt xxx	8 pt xxx
1,58 mm	10 pt xxx	8,6 pt xxx	7,2 pt xxx	9,5 pt xxx	10,2 pt xxx	8,8 pt xxx	8,8 pt xxx

- Black
- Cyan
- Magenta
- Yellow