Johnson&Johnson

Tremfya® (guselkumab)

TREMFYA® Patient guide

This patient guide is intended for patients who have been prescribed TREMFYA for the treatment of **ulcerative colitis** or **Crohn's disease.**

Visit the TREMFYA patient pages
www.tremfyapotilas.fi

Password:
tremfya

Read more about the TREMFYA treatment prescribed for you

This patient guide contains important information about your treatment with TREMFYA but does not replace the advice of your doctor or healthcare professional. This guide is intended to support you in your preparation for your treatment. If you have any questions about your treatment or illness, ask your careprovider.

The contents of this guide are based on the TREMFYA package leaflet.

Content

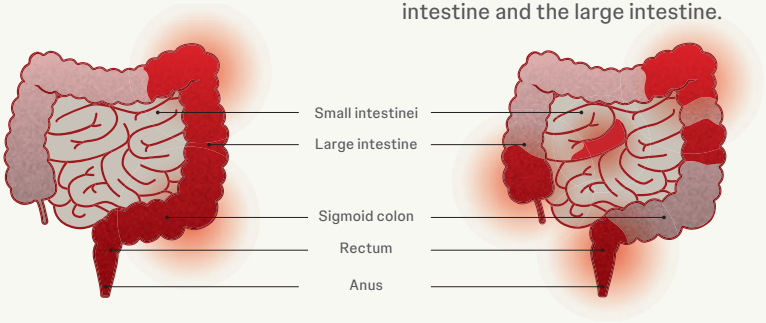
Why have you been prescribed TREMFYA?

Your doctor has prescribed TREMFYA to treat **a chronic inflammatory bowel disease (ulcerative colitis or Crohn's disease)**.

In inflammatory bowel diseases, your own immune system attacks your intestines, causing a painful inflammation.

Ulcerative colitis most commonly causes inflammation in the large intestine (colon).

Crohn's disease most commonly causes inflammation in large parts of the small intestine and the large intestine.



The symptoms of **ulcerative colitis and Crohn's disease** vary from person to person and may change over time. You may experience periods when symptoms are severe and periods when there are no symptoms at all. Always contact your doctor if you have any questions.

What is TREMFYA and how does it work?

TREMFYA is a medicine used to treat adults with moderate to severe ulcerative colitis or Crohn's disease.

In inflammatory bowel diseases (IBD), the immune system mistakenly attacks the intestinal tissue, causing chronic inflammation.

IL-23 is an inflammatory cytokine that plays a key role in several autoimmune and inflammatory diseases, such as psoriasis, psoriatic arthritis, and inflammatory bowel disease.

TREMFYA contains the active substance guselkumab, which blocks the activity of IL-23.

In this way, TREMFYA can help reduce inflammation and the symptoms associated with your disease.

Collecting TREMFYA from your pharmacy

TREMFYA is collected from the pharmacy with a prescription provided by your doctor. Please read these instructions carefully.

- When your injection date is approaching, contact your pharmacist to ensure that the medicine is available.
- Take the cooler bag and the cold pack you received from the clinic with you, as Tremfya must be kept refrigerated during transport.
- Under normal conditions, the cooler bag keeps the medicine refrigerated for up to 90 minutes.

Administration of TREMFYA

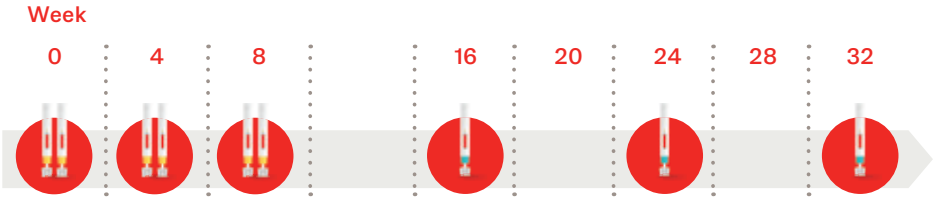
Administration of TREMFYA for the treatment of Crohn's disease and ulcerative colitis

Induction dose

The recommended dose is 2 x 200 mg by subcutaneous injection at weeks 0, 4 and 8.

Maintenance dose

Recommended dose:
100 mg by subcutaneous injection from week 16 onwards every 8 weeks.



2 x TREMFYA 200 mg PushPen
(2 x 200 mg)

Treatment initiation may also alternatively be carried out as a 200 mg intravenous infusion at weeks 0, 4, and 8.

TREMFYA 100 mg PushPen
(100 mg)

Alternatively, your doctor may prescribe a 200 mg maintenance dose administered as a subcutaneous injection starting from week 12 and thereafter at four-week intervals.

TREMFYA can also be administered using a pre-filled syringe (100 mg and 200 mg).

Guidance on injection with TREMFYA

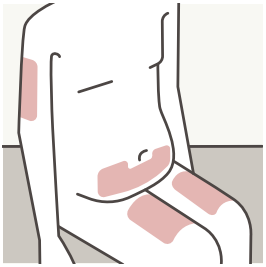
Preparing your injection

You will need the following supplies:

- 1 alcohol wipe
- 1 cotton ball or gauze pad
- 1 plaster
- 1 sharps disposal container
  (See section on how to dispose of TREMFYA, p. 10)

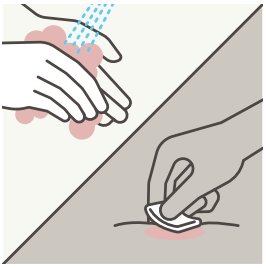
01

Make sure the package is not damaged. Check the expiry date and let the medicine reach room temperature for 30 min before administering TREMFYA.



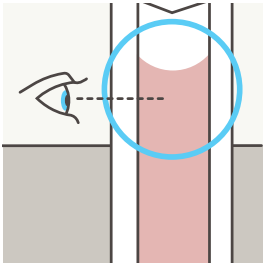
02

Choose the injection site:
front of thighs, lower abdomen or back of upper arm (if your caregiver is giving the injection). Avoid an area of approximately 5 cm from your navel.



03

Wash your hands with soap and warm water and clean the injection site with an alcohol swab.



04

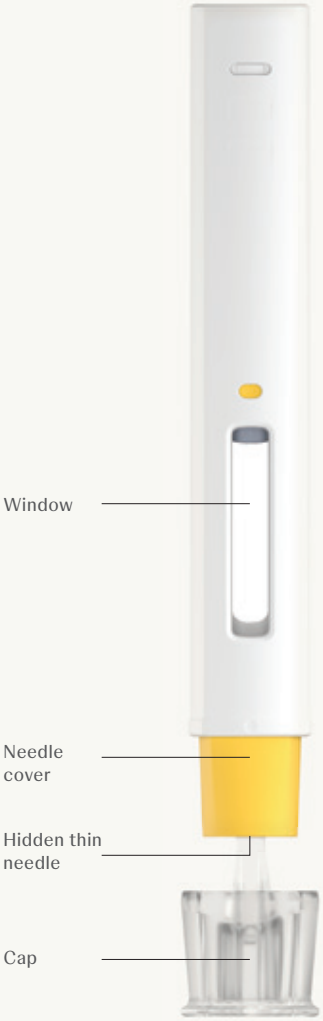
Inspect liquid in window.
It should be colorless to slightly yellow and may contain some small white to bright particles.
It may also contain air bubbles.

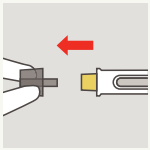
TREMFYA PushPen (Pre-filled pen)

100 mg and 200 mg PushPen

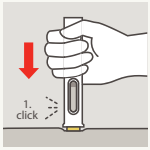
These instructions apply to both the TREMFYA 100 mg PushPen (green needle cover) and the TREMFYA 200 mg PushPen (yellow needle cover).

Watch the injection video



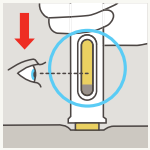


Pull the cap straight off and inject within 5 minutes. It is normal to see a few drops of liquid. Do not put the cap back on and do not use the PushPen if it falls after removing the cap. Do not touch the needle cover.



Place the PushPen with the needle cover onto the skin with the window facing you. Push the pen against your skin and you will hear a first click. Do not lift the PushPen from your skin while injecting.

Keep holding the PushPen firmly against the skin for about 10 seconds to hear a second click.



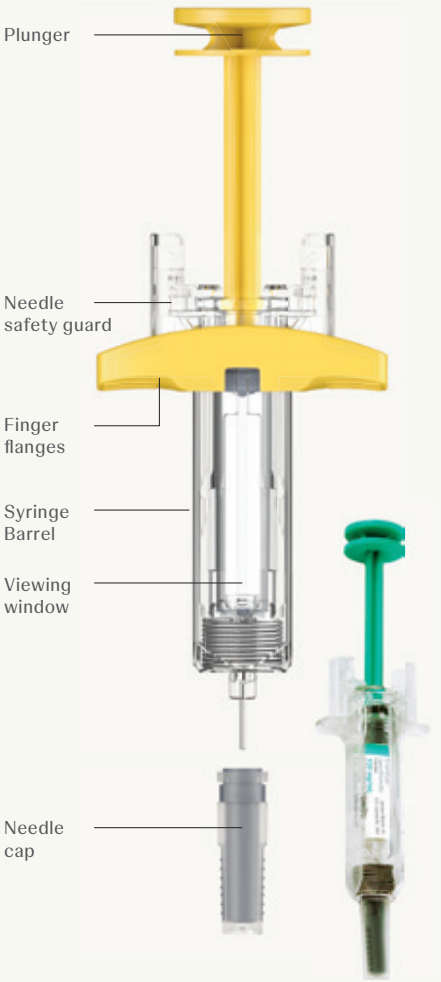
Keep holding the pen firmly against the skin. The injection is completed when the yellow plunger stops moving and fills the window. Lift the pen straight up.

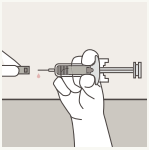
Note: If you have been prescribed a dose that requires two injections, repeat the steps above using the second PushPen. Choose a different injection site or leave at least 5 cm between the injection sites.

TREMFYA pre-filled syringe

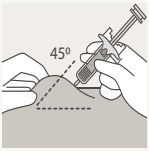
100 mg and 200 mg syringe

These instructions apply to both the 100 mg (green plunger syringe) and the 200 mg (yellow plunger syringe) pre-filled syringes.

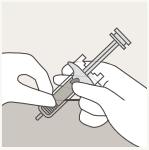




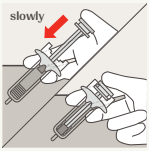
Remove the needle cap and administer the injection within 5 minutes. It is normal to see a few drops of liquid. Do not hold the syringe by the plunger or pull it at any stage. Do not put the needle cap back on, do not touch the needle, and do not allow it to touch any surface. Do not use the syringe if it is dropped.



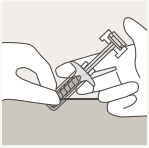
Place your thumb, index finger, and middle finger just below the finger flanges. With your other hand, pinch the skin at the injection site. Place the syringe against the skin at approximately a 45-degree angle. Insert the needle into the skin with a quick motion.



Release the pinched skin and move your hand to a new position. With your free hand, grasp the body of the syringe.



Slowly press the plunger down until it can no longer be pressed. You will feel slight resistance as you press the plunger.



Stop pressing the plunger. The needle safety guard will automatically move into place and lock, withdrawing the needle from the skin.

Note: If you have been prescribed a dose that requires two injections, repeat the steps above using the second pre-filled syringe. Choose a different injection site or leave at least 5 cm between the injection sites.

After the injection

- A small amount of blood or fluid may be visible at the injection site.
- Press the injection site with a cotton ball or gauze pad until bleeding stops. Do not rub the injection site.
- Cover the injection site with an adhesive bandage if necessary.

How to dispose of and return TREMFYA

Each administration set of TREMFYA is for single use only.

- Immediately after use, dispose of the used administration device in a sharps disposal container or return the administration device according to the Safe Returns program.
- Dispose of the filled container as instructed by your doctor or nurse.

Safe Returns

- Safe Returns is a convenient solution for patients who self-inject TREMFYA at home and wish to return used devices for disassembly and sorting.
- Used devices are returned via regular mail in a return envelope.
- Returning used devices does not incur any costs or paperwork for the patient.
- The returned devices are disassembled and sorted in a safe manner, helping to prevent disposal and incineration with household waste.

Safe Returns

Scan the QR code and read more!

safereturns.fi

Storage of TREMFYA

TREMFYA must be stored at refrigerator temperature, also during transport.

Store TREMFYA in its original package, protected from light and out of the sight and reach of children.

Store TREMFYA in a refrigerator (2–8 °C). Do not freeze.Remove the package from the refrigerator before use and allow it to reach room temperature by waiting 30 minutes. If you suspect that the medicine has been kept outside the refrigerator for longer than recommended, place the PushPen pre-filled pen back in the refrigerator and contact your healthcare provider for advice as soon as possible.

Do not shake.

Do not use TREMFYA after the expiry date (EXP) stated on the label and carton. The expiry date refers to the last day of the stated month.

Do not use TREMFYA if you notice that the medicine is cloudy, discoloured, or contains large particles.

Possible side effects

Like all medications, also TREMFYA can cause side effects, although not everyone will get these. It is important to report any side effects to your doctor or nurse.

- The most common side effect with TREMFYA is respiratory track infection.
- If you notice any symptoms suggestive of a possible serious allergic reaction or infection, stop treatment with TREMFYA and report it to your to your care giver immediately.
- Please refer to the package leaflet for more detailed information about possible side effects. You can access the TREMFYA package leaflet via the QR code provided:

Refer to TREMFYA package leaflet

- You can always contact your care giver if you have any questions about your treatment or if you experience side effects. You can also report side effects directly to Johnson & Johnson or Fimea.

Johnson & Johnson medical information
020 753 1300
jacfi@its.jnj.com

Fimea, Adverse drug reaction registry
PO BOX 55
00034 FIMEA
www.fimea.fi

Other considerations

TREMFYA and other medicines

Tell your doctor if you are taking, have recently taken, or might take any other medicines. You should also tell your doctor if you have recently received or are about to receive a vaccine. While you are being treated with TREMFYA®, you should not receive live vaccines.

Pregnancy and breast-feeding

- You should not use TREMFYA if you are pregnant, as there is no data on the effects of TREMFYA during pregnancy. Use adequate contraception and avoid becoming pregnant during treatment with TREMFYA and for at least 12 weeks after the last TREMFYA dose.
  Talk to your doctor if you are pregnant or or planning a pregnancy.
- Talk to your doctor if you are breast-feeding or you are planning to breastfeed. You can decide together the best way to act.

Traveling with TREMFYA

- Talk about your travel plans with with your care giver. Tremfya dosing or treatment plan may be adapted to your trip to avoid the need to bring your device with you.

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

Support is available

You are not alone with your condition.

The Finnish IBD patient association (Suolistosairaudet ry) offers peer support both online and through nationwide local associations:

www.suolistosairaudet.fi

Reliable additional information about these conditions is also available, for example, at:

www.terveyskirjasto.fi **www.terveyskylä.fi**

You can write the contact details of your treating unit here:

My TREMFYA calendar

This calendar will help you remember your next doses of TREMFYA.

DATE OF INJECTION Remember to follow the schedule of treatment prescribed by your doctor.	NOTES Describe anything unusual (for example, side effects or difficulties in giving the injection) during treatment. Tell your doctor or nurse about these at your next appointment.
INDUCTION DOSES: You will receive the first 2 doses of TREMFYA every 4 weeks. Write down the dates of the starting doses as prescribed by your doctor.	
__ / __ / ____	
__ / __ / ____	
MAINTENANCE DOSES: After you have received the induction doses, your doctor will decide the dosing interval of maintenance treatment. You will then receive injections either every 4 weeks or every 8 weeks.	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	
__ / __ / ____	

Johnson&Johnson

Johnson & Johnson, medical information

020 7531 300 jacfi@its.jnj.com

Janssen-Cilag Oy, a Johnson & Johnson company
PO BOX 15, 02621 Espoo, Finland
Tel +358 20 7531 300

CP-579046 04/2026