Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Tremfya® 10 mg/ml I.V.
Concentrate for solution for infusion

Each vial of 20 mg contains:
guselkumab 10 mg/1 ml

For information about inactive ingredients and allergens in this medicine, see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Ulcerative colitis

Tremfya 10 mg/ml I.V. is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biologic treatment.

Crohn's disease

Tremfya 10 mg/ml I.V. is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biologic treatment.

Therapeutic group:
Immunosuppressants, interleukin inhibitors.

How Tremfya works?
Tremfya contains the active ingredient 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 high levels in people with ulcerative colitis and Crohn's disease.

Ulcerative colitis

Colitis is 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. Treatment with

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.

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

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (guselkumab) or to any of the other ingredients in this medicine (as listed in section 6 – 'Additional information'). If you think you may be allergic, ask your doctor for advice before using this medicine.
- You have an active infection, including active tuberculosis.

Special warnings about using this medicine
Before treatment with Tremfya, tell your doctor if:

- you are being treated for an infection you have.
- you have an infection that does not go away, or the infection keeps coming back.
- you have tuberculosis or have been in close contact with someone with tuberculosis.
- you think you have an infection or have symptoms of an infection (see below under 'Look out for infections and allergic reactions').
- you have recently had a vaccination or if you are planning to have a vaccination during treatment with Tremfya.

If you are not sure if any of the above sections applies to you, consult your doctor, pharmacist or nurse before treatment with this medicine.

Look out for infections and allergic reactions
Tremfya may cause serious side effects, including allergic reactions and infections. You must look out for signs of these conditions during treatment with Tremfya.
Signs or symptoms of infections may include fever or flu-like symptoms, muscle aches, cough, shortness of breath, stinging/burning sensation when you urinate or urinating more often than usual, blood in your phlegm, weight loss, diarrhoea or stomach pain, warm, red or painful skin or sores on your body.
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 ‘Side effects’).
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 10 mg/ml I.V. is intended for use in adults aged 18 and up. There is no information about the effectiveness and safety of Tremfya in children and adolescents under 18 years of age. Do not use Tremfya in children and adolescents under the age of 18.

Tests and follow-up
As directed by your doctor, you may need to have blood tests to check if you have high levels of liver enzymes before and while you use Tremfya. Increases in liver enzymes may appear more frequently in patients receiving Tremfya every 4 weeks than in patients receiving Tremfya every 8 weeks (see also section 3 ‘How to use this medicine?’).

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
Additionally, if you recently had or are due to have a vaccination, inform your doctor. You should not receive certain type of vaccines (live vaccine) while being treated with Tremfya.

Pregnancy, breast-feeding and fertility
If you are pregnant, think you are pregnant, are planning to become pregnant or are breast-feeding, consult your doctor before using Tremfya.
Pregnancy
Do not use this medicine during pregnancy, as there is limited information about the use of this medicine in pregnant women.
Women of childbearing potential are advised to avoid becoming pregnant. Use effective contraception during treatment with Tremfya and for at least 12 weeks after receiving the last Tremfya dose.
Breast-feeding
It is not known if this medicine is excreted into breast milk and a risk to a breast-feeding infant cannot be ruled out. Consult your doctor if you need to stop treatment with this medicine or refrain from breast-feeding. The benefit of breast-feeding for your baby must be weighed against the benefit of treatment with this medicine for you.

Driving and using machines
Tremfya has no effect or a minimal effect on your ability to drive a car and operate machines.

Important information about some of this medicine’s ingredients

Tremfya contains polysorbate 80
This medicine contains 10 mg of polysorbate 80 in each vial, which is equivalent to 0.5 mg/ml.
Polysorbate may cause allergic reactions. Tell your doctor if you have any known allergies.

Tremfya contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.
However, Tremfya is mixed with a solution that contains sodium prior to administration. Talk to your doctor if you eat a low sodium diet.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:
Ulcerative colitis
Treatment start:
The first dose of Tremfya is 200 mg, and it 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.
Maintenance therapy:
A maintenance dose of Tremfya, 100 mg or 200 mg, will be given by injection under the skin (subcutaneous injection). Your doctor will determine 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.

Crohn's disease
Treatment start:
Treatment start can be given either by intravenous infusion or by subcutaneous administration:
- Intravenous infusion: The first dose of Tremfya is 200 mg, and it 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 sites 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, 100 mg or 200 mg, will be given by injection under the skin (subcutaneous injection). Your doctor will determine 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.

Do not exceed the recommended dose.

If you used too much medicine
If you received too much Tremfya or your dose was administered earlier than prescribed, inform your doctor.
If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
If you have forgotten to inject a dose of Tremfya, inform your doctor.

If you stop using this medicine
You should not stop using Tremfya without speaking to your doctor first. If you stop the treatment, your symptoms may come back.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects
As with any medicine, using Tremfya may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

<u>Serious side effects</u>
Tell your doctor or seek medical help immediately if any of the following side effects appears:
Serious allergic reactions <u>(may affect up to 1 in 100 users)</u> – 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

<u>Additional side effects</u>
The following side effects are mild to moderate. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse immediately.
Very common side effects (effects that appear in more than one in ten users)
- respiratory tract infections

Common side effects (effects that appear in 1-10 in 100 users)
- headache
- joint pain (arthralgia)
- diarrhoea
- increased level of liver enzymes in the blood

- skin rash

Uncommon side effects (effects that appear in 1-10 in 1,000 users)
- 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)
- urticaria (hives)
- redness, irritation or pain at the injection site

Rare side effects (effects that appear in 1-10 in 10,000 users)
- allergic reaction

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?
- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator at 2°C-8°C. Do not freeze.
- Keep the vial in the original carton in order to protect from light.
- After dilution: The diluted solution may be kept at room temperature for up to 10 hours. The infusion should be completed within 10 hours of dilution in the infusion bag.
- The medicine is for single use.
- Do not shake.
- Do not use this medicine if you notice that the solution is cloudy, discoloured or contains large particles.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer needed. These measures will help protect the environment.

6. Additional information
In addition to the active ingredient, this medicine also contains:
Sucrose, L-histidine monohydrochloride monohydrate, L-histidine, polysorbate 80, L-methionine, EDTA disodium dihydrate and water for injections.

What the medicine looks like and contents of the pack:
A clear, colourless to light yellow solution.
Each pack contains one 20 ml vial.

Manufacturer's name and address: Janssen Cilag-International NV
Turnhoutseweg 30, B-2340, Beerse, Belgium

Registration holder's name and address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel

Registration number of the medicine in the Ministry of Health's National Drug Registry: 180-29-38394

Approved in September 2025

The following information is intended for medical staff only.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Tremfya 10 mg/mL I.V. (200 mg/20 mL)

Tremfya solution for intravenous infusion must be diluted, prepared and infused by a healthcare professional using aseptic technique. Tremfya does not contain preservatives. Each vial is for single use only.

Inspect Tremfya visually for particulate matter and discolouration prior to administration. Tremfya is a clear and colourless to light yellow solution that may contain small translucent particles. Do not use if the liquid contains large particles, is discoloured or cloudy.

Instructions for Dilution and Administration

Add Tremfya to a 250 mL intravenous infusion bag of 0.9% Sodium Chloride Injection as follows:

1. Withdraw and then discard 20 mL of the 0.9% Sodium Chloride Injection, from the 250 mL infusion bag which is equal to the volume of Tremfya to be added.

2. Withdraw 20 mL of Tremfya from the vial and add it to the 250 mL intravenous infusion bag of 0.9% Sodium Chloride Injection for a final concentration of 0.8 mg/mL. Gently mix the diluted solution. Discard the vial with any remaining solution.
3. Visually inspect the diluted solution for particulate matter and discolouration before infusion. Infuse the diluted solution over a period of at least one hour.
4. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein binding filter (pore size 0.2 micrometre).
5. Do not infuse Tremfya concomitantly in the same intravenous line with other medicinal products.
6. Dispose any unused medicinal product in accordance with local requirements.