

## **Package leaflet: Information for the user**

### **Tremfya 200 mg concentrate for solution for infusion** 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 moderate to severe ulcerative colitis in adults, 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 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, 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**

- 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 10 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.

### **Tremfya contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

However, before Tremfya is given to you, it is mixed with a solution that contains sodium. Talk to your doctor if you are on a low salt diet.

## **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 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.

#### Ulcerative Colitis

#### **Treatment start:**

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 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**

Tremfya 200 mg concentrate for solution for infusion is given in a hospital or clinic and patients should not need to store or handle it.

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

Keep the vial 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.

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 vial contains 200 mg of guselkumab in 20 mL solution.
- The other ingredients are EDTA disodium dihydrate, histidine, histidine monohydrochloride monohydrate, methionine, 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 infusion.

Each pack contains 1 vial.

### **Marketing Authorisation Holder**

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50-100 Holmers Farm Way

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**Manufacturer**

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**Tremfya 200 mg concentrate for solution for infusion**  
guselkumab

The following information is intended for healthcare professionals 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 200 mg/20 mL (10 mg/mL) Vial for Intravenous Infusion

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 colorless 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 micrometer).
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.