

## Package leaflet: Information for the user

### Tremfya 100 mg solution for injection in pre-filled pen guselkumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### **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 psoriasis.

Tremfya is used to treat adults with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin and nails.

Tremfya can improve the condition of the skin and appearance of nails and reduce symptoms, such as scaling, shedding, flaking, itching, pain and burning.

#### **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.

### **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. 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.

Signs 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, which can include symptoms of hives and shortness of breath, have occurred with Tremfya (see “Serious side effects” in section 4).

### **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.

## **3. How to use Tremfya**

Always use this medicine exactly as your doctor or nurse has told you. Check with your doctor, nurse 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.

- The dose is 100 mg (the content of 1 pre-filled pen) given by injection under the skin (subcutaneous injection). This may be given by your doctor or nurse.
- 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. However, 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, symptoms of psoriasis may come back.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **Serious side effects**

Tell your doctor or seek medical help immediately if you get any of the following side effects:

**Possible serious allergic reaction** - 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

#### **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.

Some side effects are very common (may affect more than 1 in 10 people):

- upper respiratory infections

Some side effects are common (may affect up to 1 in 10 people):

- headache
- joint pain (arthralgia)
- diarrhoea
- stomach flu (gastroenteritis)
- redness at the injection site
- hives
- fungal infection of the skin, for instance between the toes (e.g., athlete's foot)
- herpes simplex infections

Some side effects are uncommon (may affect up to 1 in 100 people):

- pain at the injection site
- allergic reaction
- skin rash

### **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.

**In the UK**, you can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

**In Ireland**, you can also report side effects directly via: HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

**In Malta**, report side effects to: ADR Reporting  
Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

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 pre-filled pen label and on the outer carton after “EXP”. The expiry date refers to the last day of that month.

Keep the pre-filled pen in the outer carton in order to protect it 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 pen 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 pen contains 100 mg of guselkumab in 1 mL solution.
- The other ingredients are histidine, histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injections.

### **What Tremfya looks like and contents of the pack**

Solution for injection (injection). Tremfya is a clear, colourless to light yellow solution. It is supplied as a carton pack containing one single-dose pre-filled pen and as a multipack containing 2 (2 packs of 1) single-dose pre-filled pens. Not all pack sizes may be marketed.

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**This leaflet was last revised in February 2019**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>.

# Instructions for use

## Tremfya

### Pre-filled pen



SINGLE-USE DEVICE

## Important

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 pen.

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



## Storage information

Store in refrigerator at 2° to 8°C.

**Do not** freeze.

**Keep Tremfya and all medicines out of reach of children.**

**Do not** shake your pre-filled pen at any time.



## 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.

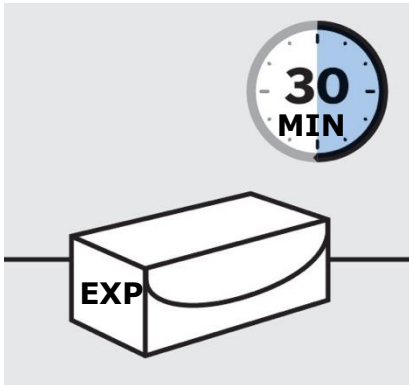
## Pre-filled pen at-a-glance



### 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 pen from the refrigerator.

Keep pre-filled pen 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 expiration date ('EXP')** on the carton.

**Do not** use if the expiration date has passed.

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

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



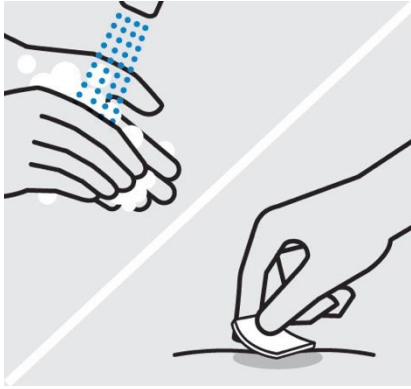
### Choose injection site

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 (if a caregiver is giving you the injection)

**Do not** inject into skin that is tender, bruised, red, scaly, hard or has scars or stretch marks.





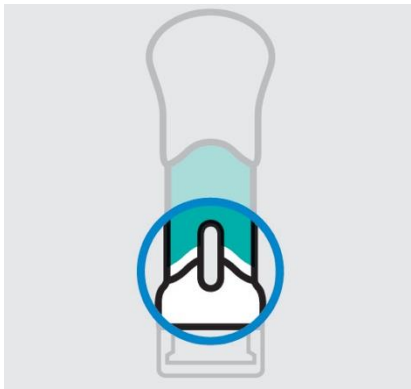
## **Wash hands**

Wash your hands well with soap and warm water.

## **Clean injection site**

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 in window**

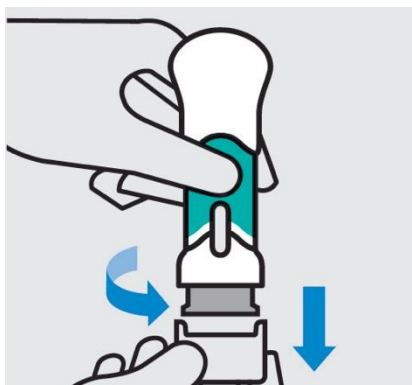
Take the pre-filled pen out of the carton.

Check the liquid in the 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 pen.

## 2. Inject Tremfya using the pre-filled pen



### **Twist and pull off bottom cap**

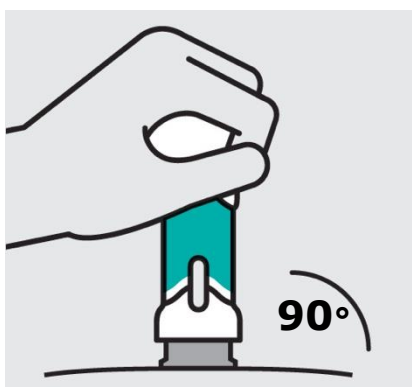
Keep hands away from the needle guard after the cap is removed.

**Inject within 5 minutes of removing the cap.**

**Do not** put the cap back on, this could damage the needle.

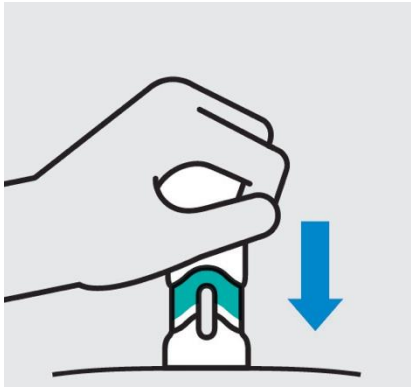
**Do not** use the pre-filled pen if it is dropped after removing the cap.

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



### **Place on skin**

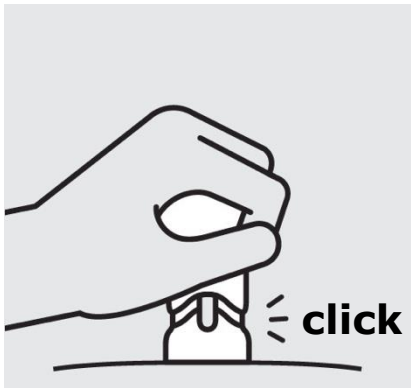
Position the pre-filled pen straight onto the skin (about 90 degrees relative to injection site).



### **Push handle straight down**

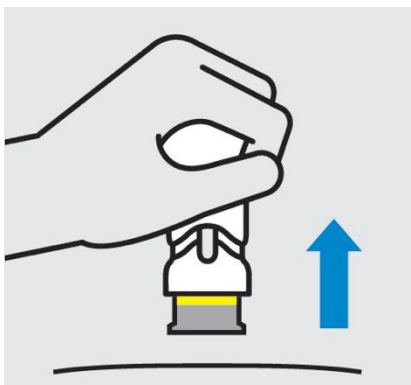
Medication injects as you push. Do this at a speed that is comfortable for you.

**Do not** lift the pre-filled pen during the injection. The needle guard will lock and the full dose will not be delivered.



### **Complete injection**

Injection is complete when the handle is pushed all the way down, you hear a click, and the green body is no longer visible.



### **Lift straight up**

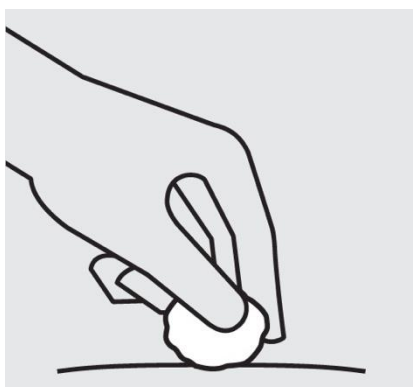
The yellow band indicates that the needle guard is locked.

### 3. After your injection



#### **Throw the used pre-filled pen away**

Put your used pre-filled pen 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.



#### **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!