

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

### **Tremfya 100 mg PushPen solution for injection in pre-filled pen 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 psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease.

##### **Plaque 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.

##### **Psoriatic arthritis**

Tremfya is used to treat a condition called "psoriatic arthritis", an inflammatory disease of the joints, often accompanied by plaque psoriasis. If you have psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines or in case of intolerance, you will be given Tremfya to reduce the signs and symptoms of the disease. Tremfya can be used alone or with another medicine named methotrexate.

Using Tremfya in psoriatic arthritis will benefit you by reducing the signs and symptoms of the disease, slowing down the damage to the cartilage and bone of the joints and improving your ability to do normal daily activities.

##### **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.

### **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.

## **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 0.5 mg of polysorbate 80 in each pre-filled pen 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.

#### Plaque psoriasis

- 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.

#### Psoriatic arthritis

- 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 receive the next dose 4 weeks later, and then every 8 weeks. For some patients, after the first dose, Tremfya may be given every 4 weeks. Your doctor will decide how often you may receive Tremfya.

#### 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.

#### 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 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 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 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 (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 pen and in multipacks comprising 2 cartons, each containing 1 pre-filled pen. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

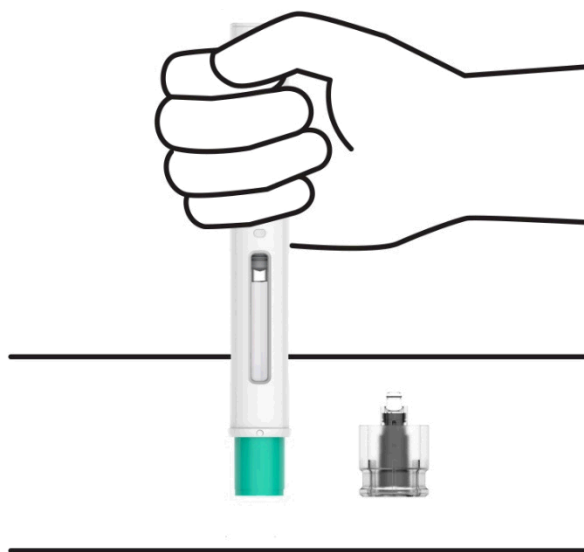
Janssen-Cilag Ltd  
50-100 Holmers Farm Way  
High Wycombe  
Buckinghamshire  
HP12 4EG  
UK

### **Manufacturer**

Janssen Biologics B.V.  
Einsteinweg 101  
2333CB Leiden  
The Netherlands

**This leaflet was last revised in 12/2025**

**Instructions for use  
Tremfya  
100 mg PushPen pre-filled pen**



**SINGLE-USE DEVICE**

**Important**

Tremfya comes in a single-use pre-filled pen containing one 100 mg dose.

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.

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

**Storage information**

Store in refrigerator at 2° to 8°C.

**Do not** freeze.

**Do not** shake your pre-filled pen.

**Keep your pre-filled pen in the original carton to protect from light and physical damage.**

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

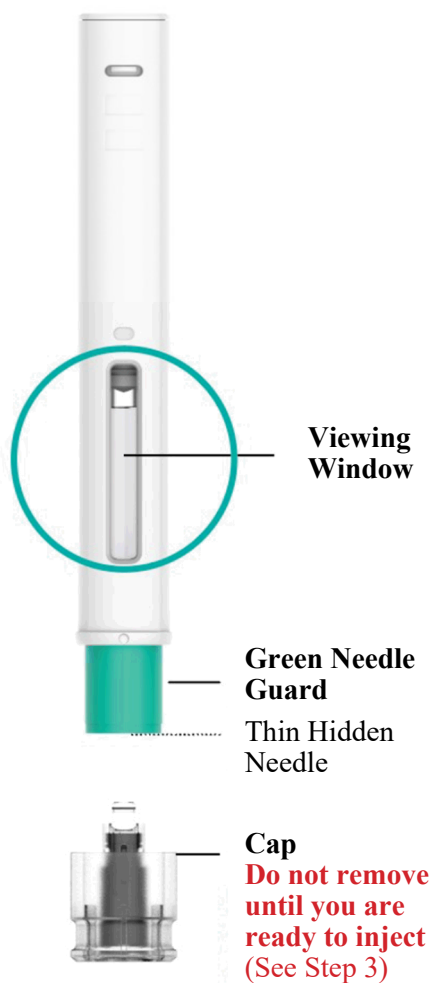
**Need help?**

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.



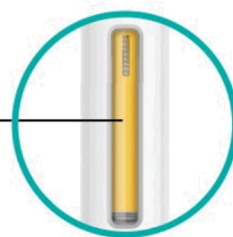
## Pre-filled pen at-a-glance

### Before use



### After use

Yellow plunger rod fills the viewing window



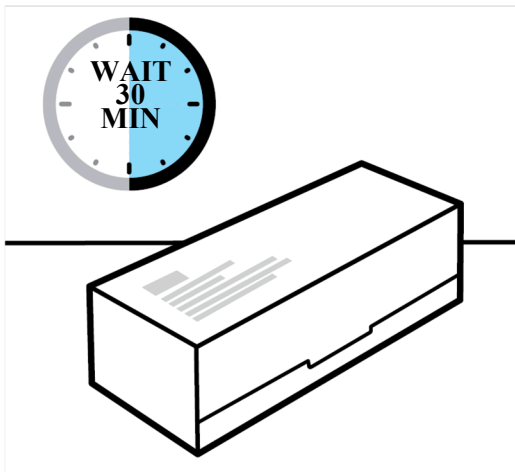
### You will need:

- 1 pre-filled pen

### Not provided in the carton:

- Alcohol swabs
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps container (See Step 4)

## 1. Get ready



### **Allow Tremfya to come to room temperature**

Remove the carton from the refrigerator and let the carton sit on a flat surface at room temperature for approximately **30 minutes** before use.

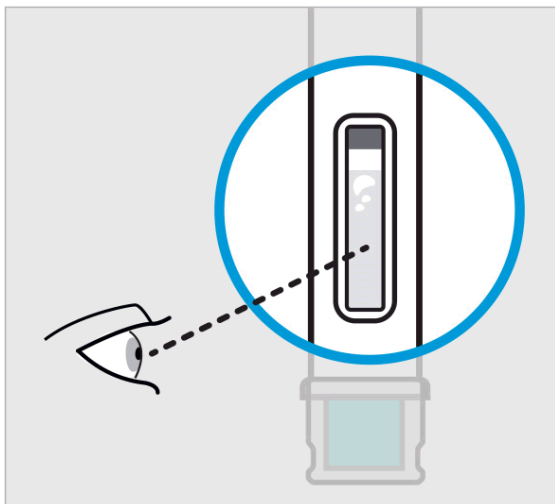
**Do not** warm the pre-filled pen any other way.

**Check the expiry ('EXP') date** on the carton.

**Do not** use the pre-filled pen 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 pen.

## 2. Prepare for your injection



### **Inspect liquid in window to see that it is clear to slightly yellow**

Take the pre-filled pen 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
- discoloured or
- has large particles

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

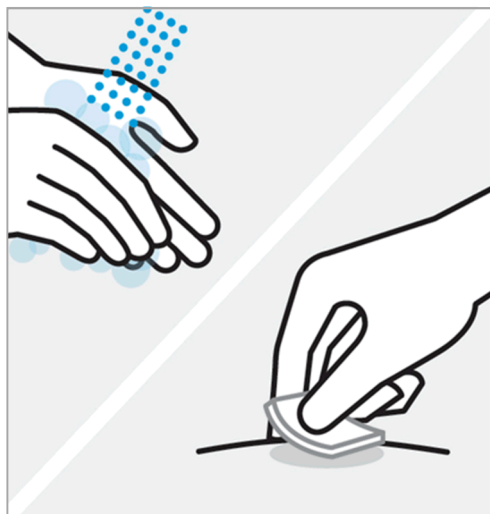


### **Choose injection site**

Select from the following areas for your injection:

- Front of thighs
- Lower stomach area (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, thick or hard. Avoid areas with scars or stretch marks.



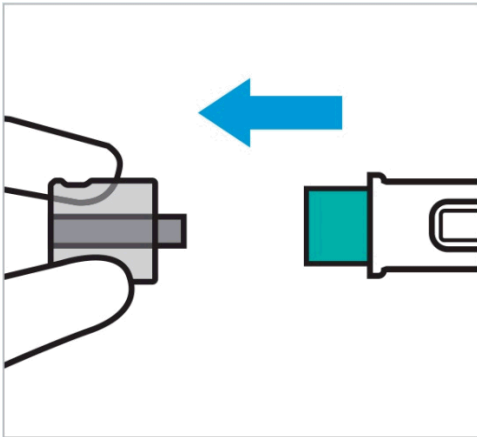
### **Wash hands and clean injection site**

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 pen



**Remove cap when you are ready to inject**

**Do Not Touch Green Needle Guard!**

This may start the injection and you will not receive the dose.

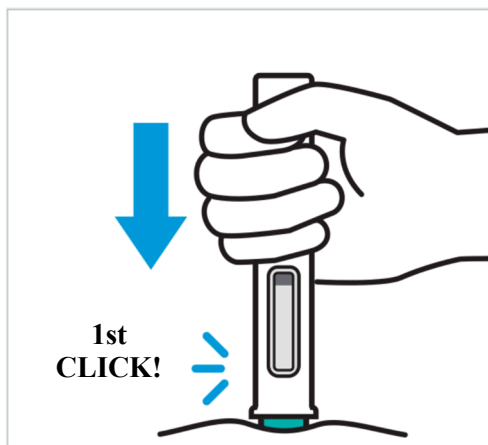
Pull the cap straight off. It is normal to see a few drops of liquid.

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

**Do not** put the cap back on as this may 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.



**Position pre-filled pen straight onto the injection site then push and hold pre-filled pen**

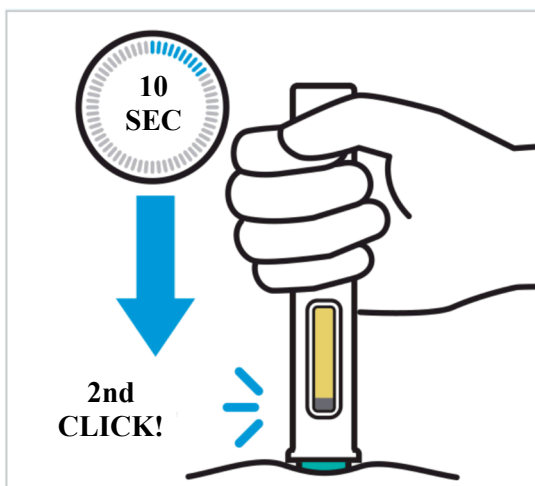
**Do Not Lift The Pre-Filled Pen During Injection!**

If you do, the green needle guard will lock and the full dose will not be delivered.

Position the pre-filled pen straight onto the injection site with the green needle guard against the skin and the viewing window facing you.

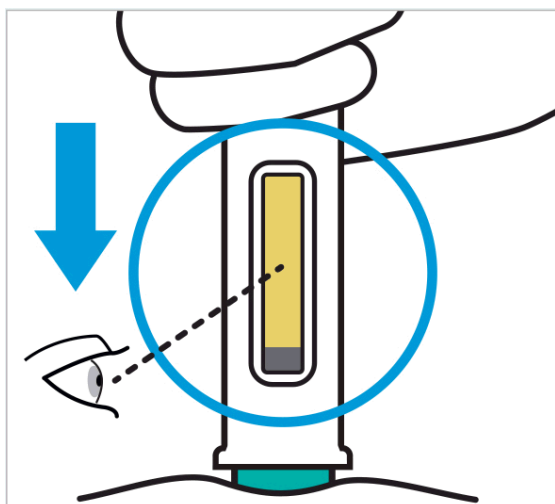
Press down on the pre-filled pen and keep holding it down against the skin.

**You will hear the first click.**



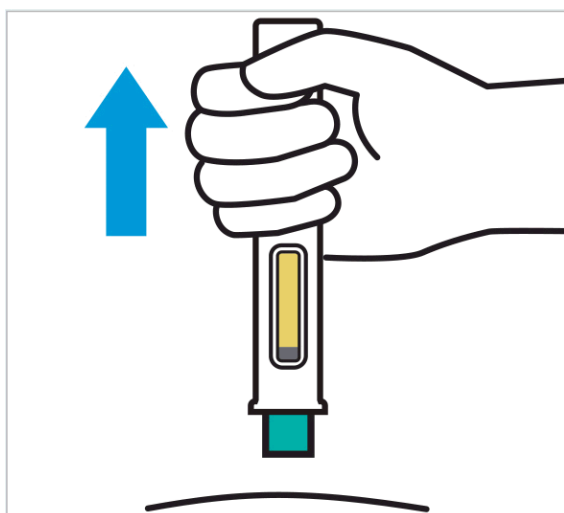
**Keep holding the pre-filled pen firmly against the skin for about 10 seconds to hear a second click**

**You are almost done.**



**Keep holding firmly against the skin and confirm the injection is complete**

**The injection is complete when the yellow plunger rod stops moving and fills the viewing window.**



**Lift straight up**

#### **4. After your injection**



##### **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!



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

Put your used pre-filled pen and cap 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 pen in your household waste.

**Do not** recycle your used sharps disposal container.