

## Package leaflet: Information for the user

### Tremfya 45 mg/0.45 mL solution for injection in pre-filled pen

For paediatric patients less than 40 kg  
guselkumab

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you. This leaflet has been written for the person taking the medicine. If you are the parent or caregiver who will give Tremfya to a child, please read this information carefully.**

- 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.

#### Plaque psoriasis in children

Tremfya is used to treat children 6 years of age and older with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin.

Tremfya can improve the condition of the skin and reduce signs and symptoms, such as scaling and redness.

### 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. Children need to be brought up to date with age-appropriate vaccines prior to beginning 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.

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 and hives, have occurred with Tremfya (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 less than 6 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 0.3 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.

### **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 in children from the age of 6 years**

Children weighing less than 40 kg:

- The recommended dose of Tremfya for children weighing less than 40 kg depends on their body weight. Your doctor will tell you the correct dose to use.
- A pre-filled pen containing 45 mg/0.45 mL of Tremfya is used to give your dose 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.

Children weighing 40 kg or more:

- For children weighing 40 kg or more a 100 mg pre-filled syringe is available.

At the start, your doctor or nurse will inject Tremfya. Your doctor may decide that your caregiver may be able to give Tremfya after receiving appropriate training from your doctor on how to inject Tremfya. Talk to your doctor or nurse if you have any questions about your injection.

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 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
- redness, irritation or pain at the injection site
- increased level of liver enzymes in the blood
- skin rash

**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 prefilled 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 45 mg of guselkumab in 0.45 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.

### **Marketing Authorisation Holder**

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

### **Manufacturer**

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

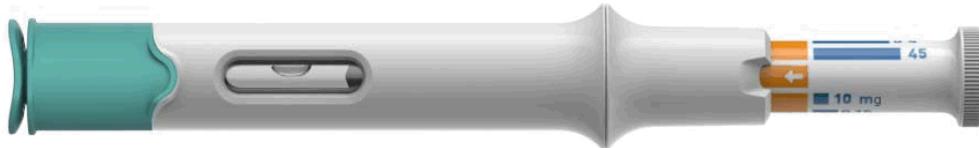
**For information in large print, tape, CD or Braille, telephone 0800 7318450**

**This leaflet was last revised in 11/2025**

**Instructions for use**  
**Tremfya**  
**45 mg/0.45 mL**  
solution for injection in pre-filled pen, VarioJect  
For paediatric use

**SINGLE-USE DEVICE**

This Instructions for Use contains information on how to inject Tremfya.



**Know your dose.**

**Important Information You Need to Know Before Injecting Tremfya**

Tremfya comes in a single-use pre-filled pen that allows you to manually set a specific, prescribed dose. **If unsure of the correct dose, contact the prescribing doctor before injecting.**

If your doctor decides that a caregiver may be able to give your injections of Tremfya at home, **they should receive training on the correct way to prepare and inject Tremfya before using the pre-filled pen.** If your caregiver has not been trained, or has any questions, please call your doctor.

Read this Instructions for Use before using the Tremfya pre-filled pen and each time you get a refill. 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 the injection and discuss any questions you may have with your doctor or nurse.

Each pre-filled pen can only be used one time. Throw away the used pre-filled pen after one dose, even if there is medicine left in it.

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



**Storage information**

Store in refrigerator at 2°C to 8°C.

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

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

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

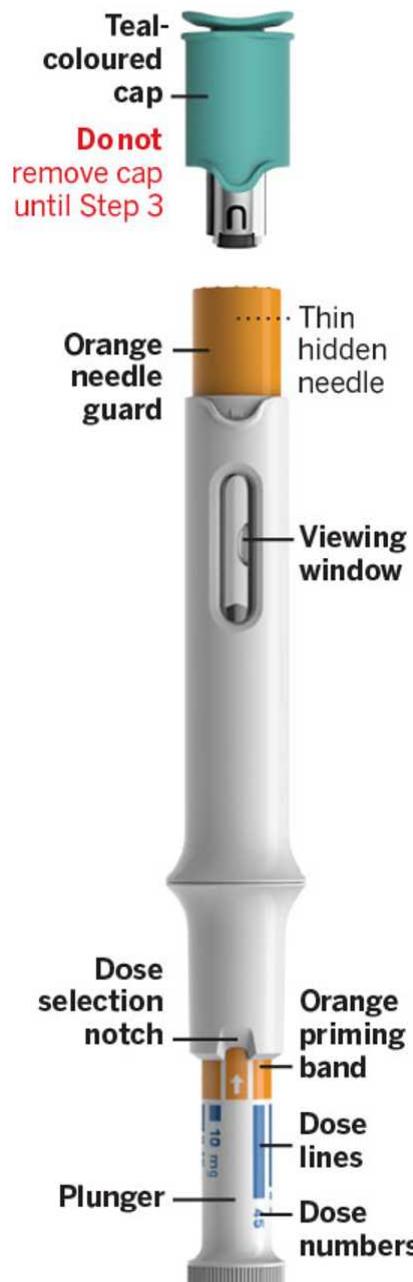
**Keep the Tremfya pre-filled pen and all medicines out of reach of children.**



## Need help?

Call your doctor to talk about any questions you may have. For additional assistance refer to the Package Leaflet for your local representative contact information.

## Pre-filled pen parts



### You will need these supplies:

- 1 Pre-filled pen

Not provided in the pre-filled pen carton:

- Alcohol swab
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps container

## 1. Get ready



### Allow Tremfya to come to room temperature and inspect carton

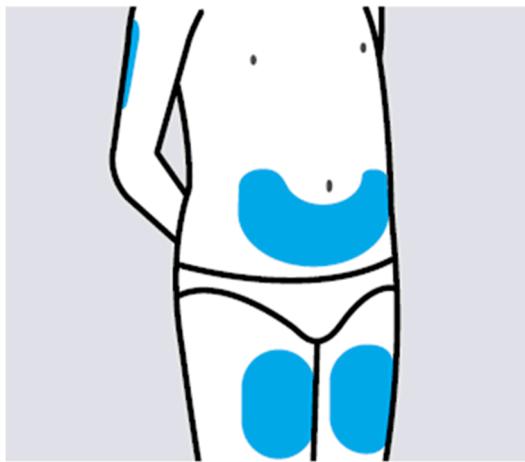
Remove the carton from the refrigerator and let the carton sit on a flat surface at room temperature for approximately **30 minutes** before use.

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

Check the expiration date ('EXP') on the carton.

**Do not** use the pre-filled pen if the expiration 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 to inject Tremfya



### Choose injection site

Select a site from the following areas for the injection:

- Front of thighs
- Lower stomach area (lower abdomen), avoiding the 5-centimetre area around the navel (belly button)
- Back of upper arms

**Do not** inject into skin that is tender, bruised, red, scaly, hard, thick, has scars, or is affected by psoriasis.

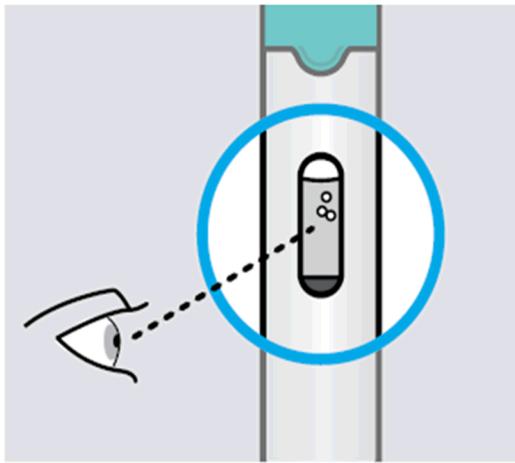


### Wash hands and Clean injection site

Wash your hands well with soap and warm water.

Wipe the chosen injection site with an alcohol swab and allow it to dry by air.

**Do not** touch, fan, or blow on the injection site after you have cleaned it.



### Inspect liquid in viewing window

Take the pre-filled pen out of the carton.

Check the liquid in the viewing window. It should be clear and colourless 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

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

### 3. Remove air bubbles

Keep the pre-filled pen pointing up during this step

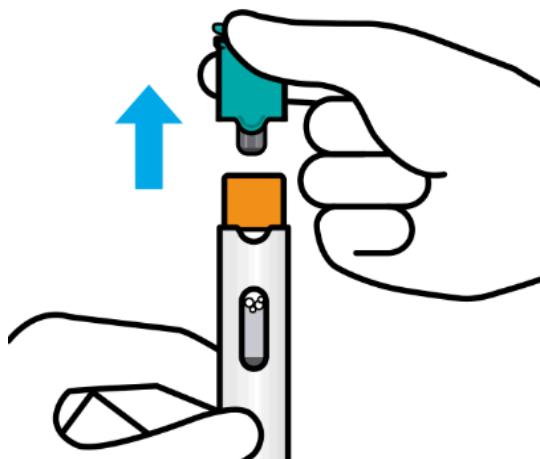


**Tap pre-filled pen to move air bubbles to the top even if you do not see any air bubbles**

Hold the pre-filled pen with the teal coloured cap pointing up.

Tap gently near the viewing window. This will cause any air bubbles to rise to the top.

**Do not** set the pre-filled pen down until air bubbles are removed.



**Remove cap**

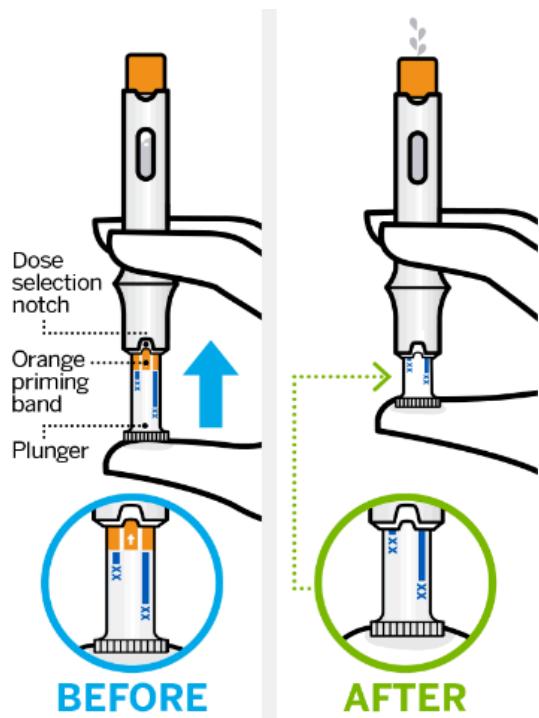
Keep holding the pre-filled pen with the teal cap pointing up, then **pull** the cap to remove.

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

Pushing the needle guard too soon may lock the pre-filled pen and you will not be able to give the dose.

**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.



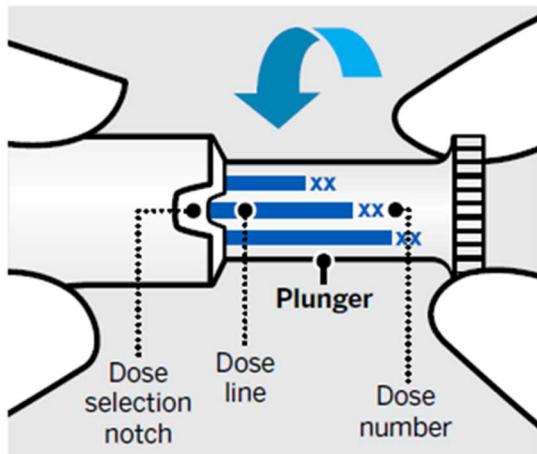
**Press the plunger until it stops to push out air bubbles**

**Keep holding the pre-filled pen with the orange needle guard pointing up.**

Confirm air bubbles are removed by checking that the orange priming band is no longer visible in the dose selection notch.

**Liquid may squirt out.** This is normal.

#### 4. Set the dose



##### Turn the plunger to set the dose

Turn the plunger until the dose line and dose number that corresponds to the prescribed dose (see table below) is in the dose selection notch as shown in the image above.

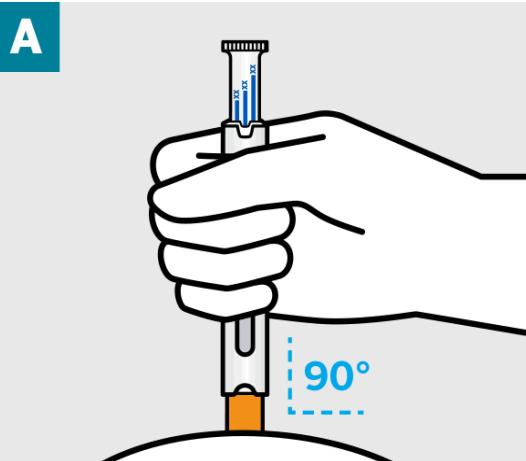
**Prescribed dose**

**Turn plunger to:**

20 mg =	20 mg
25 mg =	25
30 mg =	30
35 mg =	35
40 mg =	40
45 mg =	45

## 5. Inject Tremfya

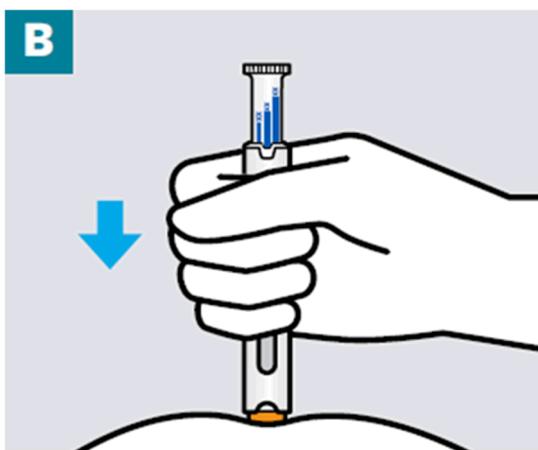
Read all sub-steps from A to D before injecting



### Position pre-filled pen straight onto the injection site

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

Continue to hold the pre-filled pen against the skin.

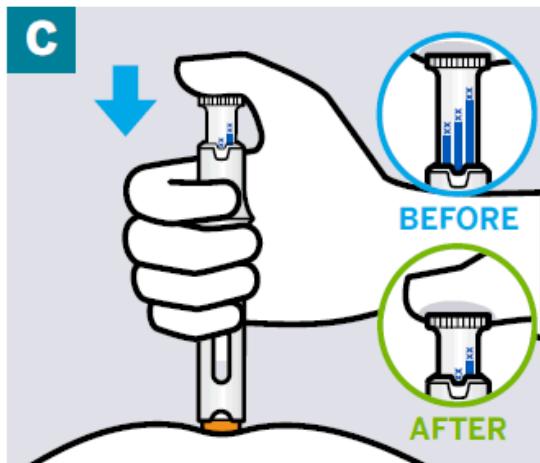


### Push pre-filled pen down to insert the needle into the skin and hold in place

**Do not** press the plunger yet.

**Do not** lift the pre-filled pen from the skin.

Push the pre-filled pen into the skin until the orange needle guard stops to insert the needle into the skin. Some orange will still be showing.



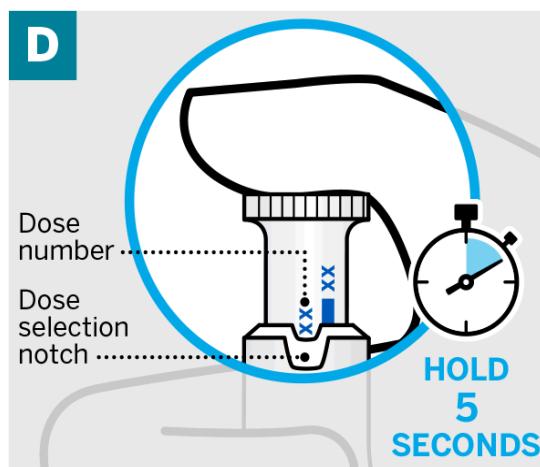
**Slowly press the plunger all the way down until it stops to inject Tremfya**

**Do not** lift the pre-filled pen from the skin during the injection.

Otherwise, the orange needle guard will lock, and you will not be able to give the full dose.

You will feel some resistance as you press the plunger. This is normal.

If a small dose is set, the plunger will only move a short distance.



**Hold and confirm injection is complete**

Hold the pre-filled pen in place and keep pushing against the skin for **5 seconds**.

**Confirm injection is complete by checking that:**

- **you cannot press the plunger down any more**
- **the selected blue dose line is no longer visible**
- **only the selected dose number is visible in the dose selection notch**

After confirming, lift the pre-filled pen from the skin.

The orange needle guard will extend and lock.

It is normal to see some liquid left in the viewing window.

## 6. After 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 injection site with a bandage.



### Dispose of the pre-filled pen

Put the used pre-filled pen in a sharps disposal container right away after use.

**Do not** throw away (dispose of) the pre-filled pen in your household waste.

Make sure you dispose of the bin as instructed by your doctor or nurse when the container is full.

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

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