

# ANDEMBRY®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using ANDEMBRY®?

ANDEMBRY® contains the active ingredient garadacimab. ANDEMBRY® is used for routine prevention of attacks of hereditary angioedema in patients aged 12 years and older.

For more information, see Section [1. Why am I using ANDEMBRY®?](#) in the full CMI.

### 2. What should I know before I use ANDEMBRY®?

Do not use if you have ever had an allergic reaction to ANDEMBRY® or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ANDEMBRY®?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ANDEMBRY® and affect how it works.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ANDEMBRY®?

- The recommended initial loading dose is 400 mg (2 x 200 mg injections) under the skin (subcutaneously) on the first day, followed by a monthly dose of 200 mg thereafter.
- The injection is administered using a pre-filled pen (auto-injector).

For more information, see Section [4. How do I use ANDEMBRY®?](#) in the full CMI.

### 5. What should I know while using ANDEMBRY®?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ANDEMBRY®.</li><li>• Call your doctor straight away or go to the Emergency Department at your nearest hospital if you have a severe allergic reaction to ANDEMBRY® with symptoms such as hives, tight chest, low blood pressure (such as feeling dizzy or light headed), or signs of anaphylaxis such as difficulty breathing or wheezing.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• ANDEMBRY® has negligible influence on the ability to drive and use machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in a refrigerator, between 2°C and 8°C, in its original carton until use, to protect it from light.</li><li>• Do not freeze.</li></ul>

For more information, see Section [5. What should I know while using ANDEMBRY®?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effects with ANDEMBRY® are reactions at the injection site, including redness, bruising and itchiness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# ANDEMBRY®

Active ingredient(s): *garadacimab*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ANDEMBRY®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ANDEMBRY®.**

Where to find information in this leaflet:

- [1. Why am I using ANDEMBRY®?](#)
- [2. What should I know before I use ANDEMBRY®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ANDEMBRY®?](#)
- [5. What should I know while using ANDEMBRY®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using ANDEMBRY®?

ANDEMBRY® contains the active ingredient *garadacimab*. ANDEMBRY® is a monoclonal antibody.

ANDEMBRY® is used in adults and children aged 12 years and older to prevent swelling attacks in patients with hereditary angioedema (HAE).

Hereditary angioedema is a rare genetic disease in which people do not produce enough (deficiency) working C1 esterase inhibitor (C1-INH) protein, leading to an overproduction of bradykinin. Bradykinin causes blood vessels to leak fluids into the surrounding tissue resulting in spontaneous and unpredictable swelling attacks as seen in HAE. These can typically occur in the hands, feet, face, abdomen, genitals, tongue and larynx (voice-box).

#### How does ANDEMBRY® work?

ANDEMBRY® prevents HAE attacks by inhibiting a protein known as factor XIIa (FXIIa) from starting the events that lead to bradykinin overproduction.

### 2. What should I know before I use ANDEMBRY®?

#### Warnings

Do not use ANDEMBRY® if:

- you are allergic to *garadacimab*, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

#### Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

#### Use in children and adolescents

ANDEMBRY® is not recommended for use in children under 12 years of age. This is because it has not been studied in this age group.

### 3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with ANDEMBRY® and affect how it works.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ANDEMBRY®.**

### 4. How do I use ANDEMBRY®?

#### How much to use

- The recommended dose of ANDEMBRY® is an initial loading dose of 400 mg administered subcutaneously as two 200 mg injections on the first day of treatment followed by a monthly dose of 200 mg thereafter.
- Follow the instructions provided and use ANDEMBRY® until your doctor tells you to stop.

#### When to use ANDEMBRY®

Your treatment will be started and managed under the supervision of a doctor experienced in the care of patients with HAE.

## How to use ANDEMBRY®

If you inject ANDEMBRY® yourself or if your caregiver injects it, you or your caregiver must carefully read and follow the Instructions for Use at the end of this Consumer Medicine Information.

- ANDEMBRY® is for injection under the skin ('subcutaneous injection').
- The injection can be given by either yourself or a caregiver.
- A doctor, pharmacist or nurse should show you how to inject ANDEMBRY® properly before you use it for the first time. Do not inject yourself or someone else until you have been trained to inject the medicine.
- Insert the needle into the fatty tissue in the belly (abdomen) or thigh.
- If somebody else gives you the injection, they can also use the upper arm.
- Change your injection site with each monthly injection.
- Use each pre-filled pen only once.
- If the pre-filled pen does not perform as intended, tell your doctor, pharmacist or nurse immediately.

### If you forget to use ANDEMBRY®

ANDEMBRY® should be used regularly at the same time each month. If you miss your dose at the usual time, inject your dose as soon as possible and then keep to your original schedule for the next dose. If you are not sure when to inject ANDEMBRY® after a missed dose, ask your doctor, pharmacist or nurse.

### If you use too much ANDEMBRY®

If you think that you have used too much ANDEMBRY®, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using ANDEMBRY®?

### Things you should do

**Call your doctor straight away or go to the Emergency Department at your nearest hospital if you:**

- have a severe allergic reaction to ANDEMBRY® with symptoms such as hives, tight chest, low blood pressure (such as feeling dizzy or light headed), or signs of anaphylaxis such as difficulty breathing or wheezing.

Remind any doctor, dentist or pharmacist you visit that you are using ANDEMBRY®.

### Things you should not do

- Do not stop using this medicine suddenly.

### Driving or using machines

ANDEMBRY® has negligible influence on the ability to drive or use machines.

### Looking after your medicine

- Store in a refrigerator, between 2°C and 8°C, in its original carton until use, to protect it from light.
- Do not freeze.
- If needed, for example when travelling, the pre-filled pen may be stored at room temperature, up to 25°C for up to 2 months.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
Injection site reactions <ul style="list-style-type: none"><li>• redness</li><li>• bruising</li><li>• itchiness</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ANDEMBRY® contains

<b>Active ingredient (main ingredient)</b>	Garadacimab
<b>Other ingredients (inactive ingredients)</b>	Histidine Arginine hydrochloride Proline Polysorbate 80 Water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ANDEMBRY® looks like

ANDEMBRY® is presented as a slightly opalescent to clear, brownish to yellow solution for injection in a pre-filled pen.

ANDEMBRY® is available as a single pack containing one 1.2 mL pre-filled pen and in multipacks of 3 cartons, each containing 1 pre-filled pen.

1.2 mL pre-filled pen (AUST R 443611)

3 x 1.2 mL pre-filled pen (AUST R 443611)

### Who distributes ANDEMBRY®

ANDEMBRY® is supplied in Australia by  
CSL Behring (Australia) Pty Ltd  
ABN 48 160 734 761  
189–209 Camp Road  
Broadmeadows VIC 3047  
Australia

### For Medical/Technical Enquiries

TOLL FREE: 1800 642 865

### For Customer Service Enquiries

TOLL FREE: 1800 063 892

customerservice@cslbehring.com.au  
www.cslbehring.com.au

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## Instructions for Use

**ANDEMBRY®**

**(garadacimab)**

**Pre-filled Pen**

### **Injection, For Subcutaneous Use**

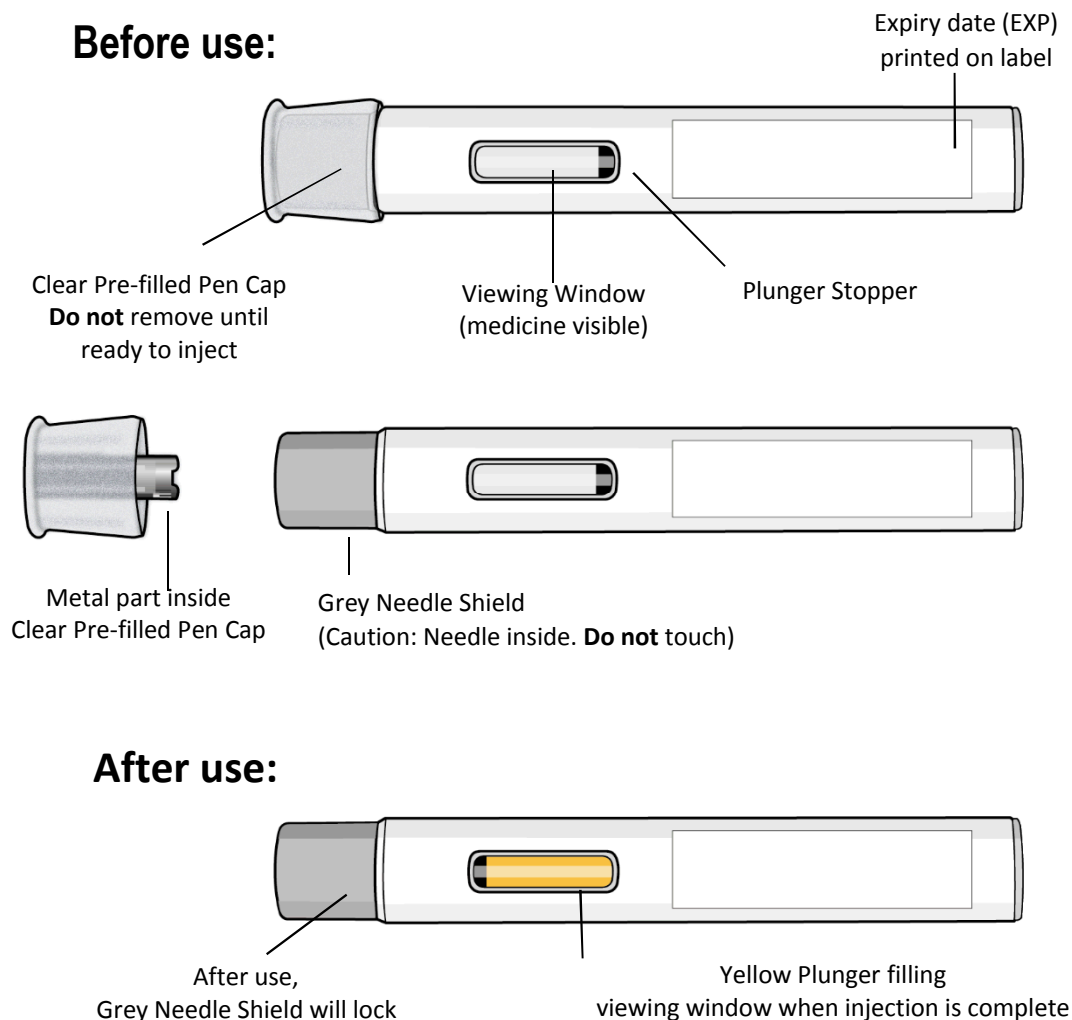
**Important:**

This pre-filled pen works differently than other injection devices. Read the Instructions for Use carefully before using it, and each time you get a new pre-filled pen as there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. In adolescent patients, administer ANDEMBRY® under the supervision of an adult.

**Make sure you have been trained by your healthcare provider before you use this pre-filled pen for the first time.**

## Parts of the Pre-filled Pen (see Figure A):

Continue to next sections to prepare and perform the injection.



**Figure A**

## Read the Following Safety Information:

- Keep the pre-filled pen in its original carton until use, to protect it from light.
  - **Do not** remove the Clear pre-filled pen Cap until you are ready to inject.
  - **Do not** put the Clear pre-filled pen Cap back on the pre-filled pen after it has been removed because this could start the injection and cause injury.
  - The pre-filled pen contains 1 dose and is for single-use only. **Do not** try to reuse the same pre-filled pen.
  - **Do not** use the pre-filled pen if the expiry date has passed.
  - The pre-filled pen is for subcutaneous (under the skin) injection only.
  - **Do not** use the pre-filled pen if it has dropped, looks damaged, has cracks, or is leaking medicine. Throw away the pre-filled pen as described in **Step 11** and use a new one.
  - **Do not** inject through clothing.
  - **Do not** touch or try to remove the grey needle shield at any time.
  - **Keep ANDEMBRY® and all medicines out of reach of children.**
- Contact your healthcare provider if you have any questions.

## How Should I Store ANDEMBRY®?

- Store ANDEMBRY® pre-filled pen in a refrigerator, between 2°C to 8°C in its original carton until use, to protect it from light.
- **Do not** freeze. If the pre-filled pen has been frozen, **do not** use the pre-filled pen even if it is thawed.
- Take the pre-filled pen out of the refrigerator 30 minutes before use, allowing it to reach room temperature.
- If needed, for example when traveling, the pre-filled pen may be stored at room temperature, up to 25°C for up to 2 months.
- If you decide to store the pre-filled pen at room temperature, you **must**:
  - Write the date you first remove the pre-filled pen from the refrigerator in the space provided on the carton to help you keep track of how long it has been stored at room temperature.
  - **Do not** put the pre-filled pen back in the refrigerator after it has reached room temperature.
  - Throw away the pre-filled pen if it has been stored at room temperature for longer than 2 months (see **Step 11. Disposing of the Pre-filled Pen**).

## Supplies needed for your Pre-filled Pen Injection (see Figure B):

Included in the carton:

- 1 Single-dose pre-filled pen

Required supplies but not included in the carton:

- 1 Alcohol pad
- 1 Cotton ball or gauze pad
- 1 sharps container or puncture-resistant container for disposal (see **Step 11. Disposing of the Pre-filled Pen**)

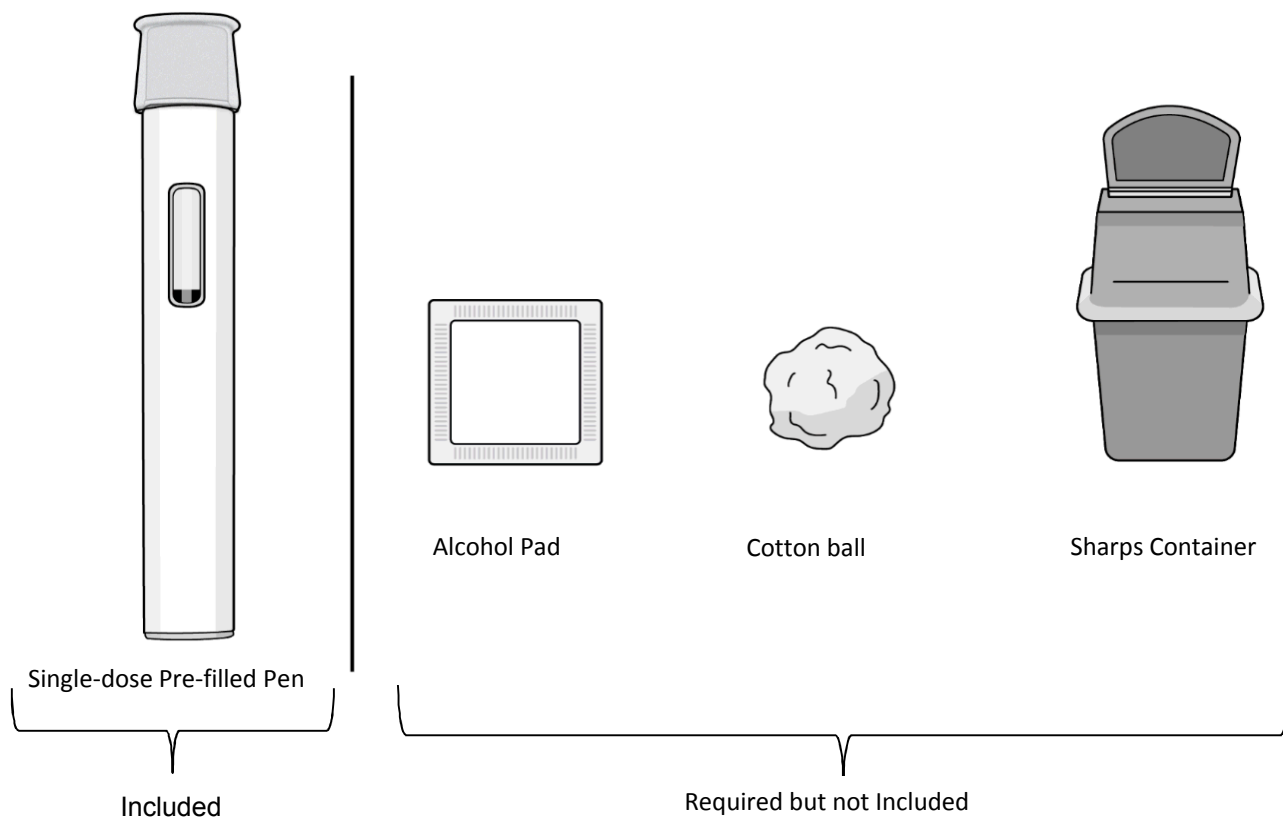


Figure B

## Preparing for an Injection

Do not remove the clear pre-filled pen cap until immediately before the injection.

### Step 1. Let the Pre-filled Pen Reach Room Temperature

- Remove the pre-filled pen from the carton and place it laying down-on a clean flat surface.
- Wait **30 minutes** for the medicine to reach room temperature if it was stored in the refrigerator (see **Figure C**).
- Injecting the medicine cold could be uncomfortable.
- **Do not** try to speed up the warming process in any way. For example, **do not** warm it in a microwave, in hot water, or leave it in direct sunlight.

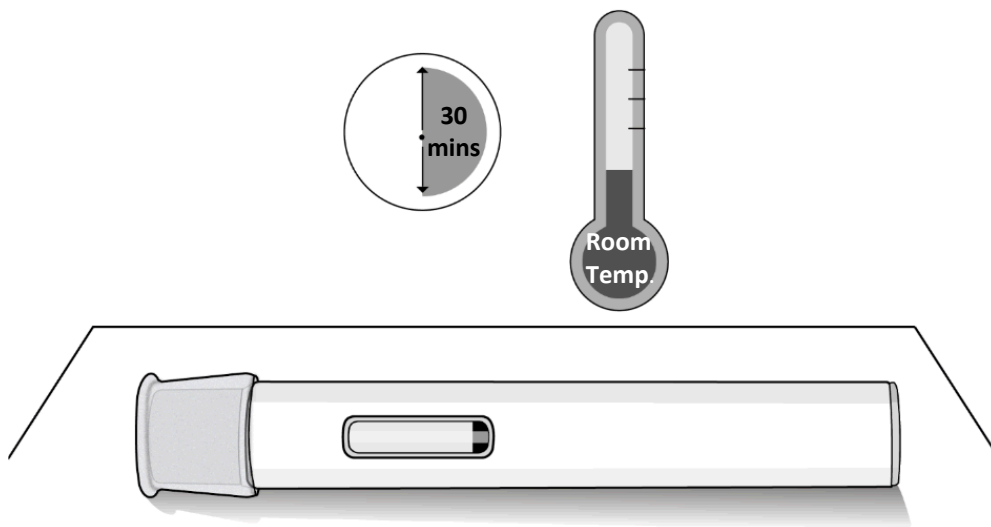
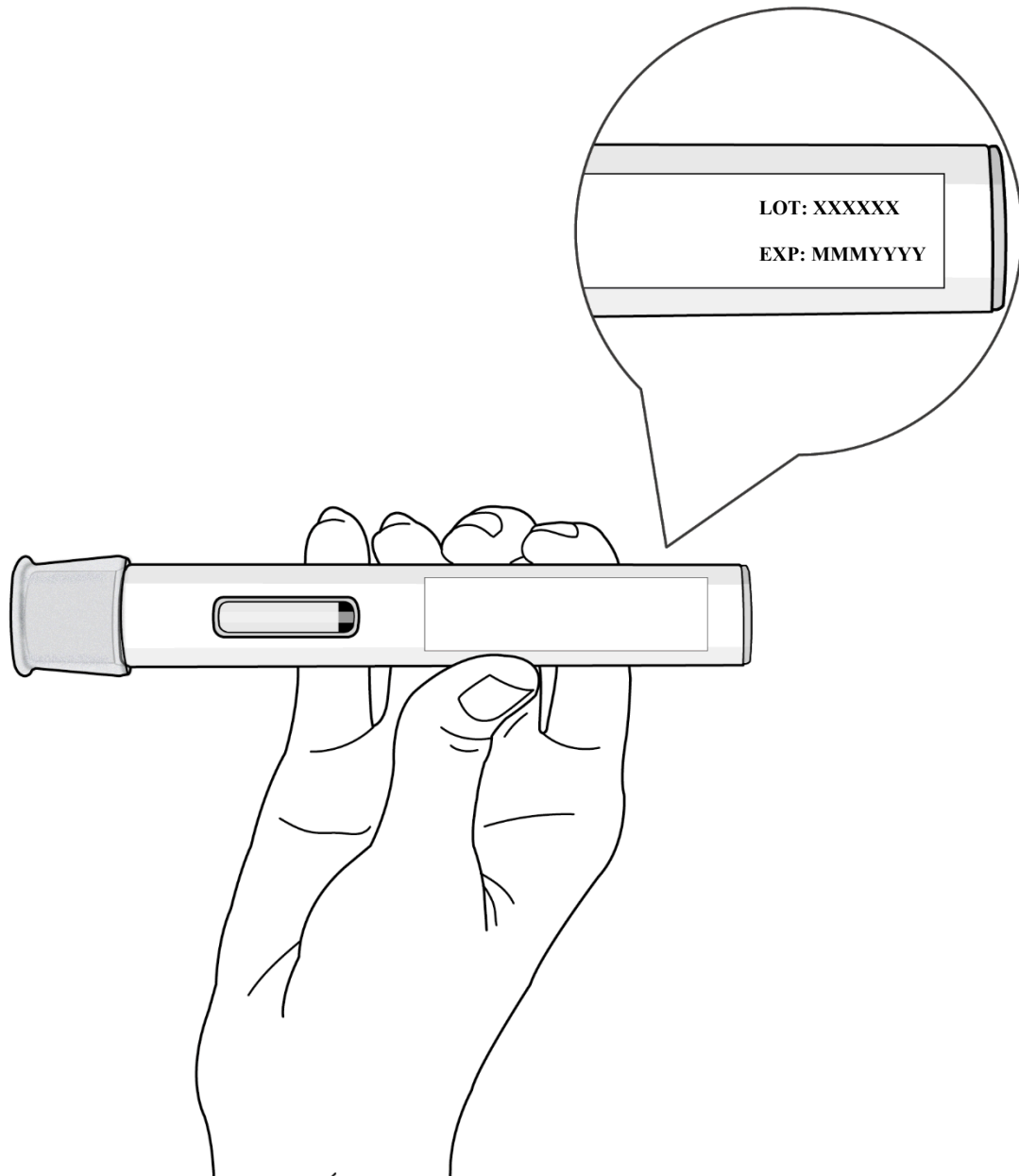


Figure C

## Step 2. Check the Expiry Date

- Check the expiry date on the pre-filled pen label (see **Figure D**).
- **Do not use** the pre-filled pen if the expiry date has passed.
- **Do not use** the pre-filled pen if stored at room temperature for longer than 2 months.
- If the expiry date has passed or if stored at room temperature for longer than 2 months, then safely dispose of the pre-filled pen and get a new one (see **Step 11. Disposing of the Pre-filled Pen**).



**Figure D**

### Step 3. Inspect the Pre-filled Pen and the medicine

- **Check** the pre-filled pen **for damage**.
- **Check the medicine** through the viewing window of the pre-filled pen (see **Figure E**).
- It is normal to see air bubbles, **do not** try to remove the air bubbles.
- The medicine should be brownish-yellow to yellow and may appear slightly opalescent to clear.
- **Do not use** the pre-filled pen, safely dispose and get a new one (see **Step 11. Disposing of the Pre-filled Pen**) if:
  - The medicine is discoloured or contains particles
  - The pre-filled pen looks damaged or has cracks
  - The pre-filled pen is leaking
  - The pre-filled pen has been dropped on a hard surface, even if it does not look damaged

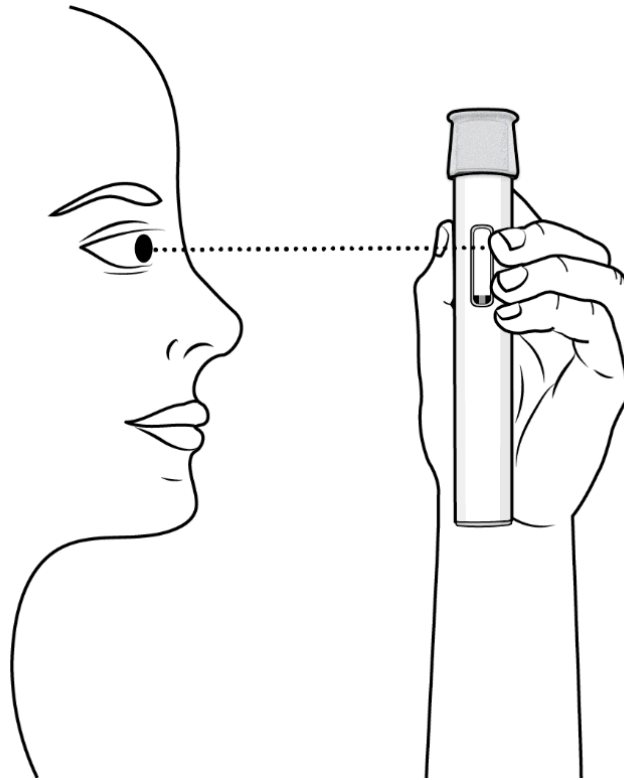


Figure E

### Choose and Prepare an Injection Site

#### Step 4. Clean your Hands

- Wash your hands well with soap and water or use hand sanitiser (see **Figure F**).

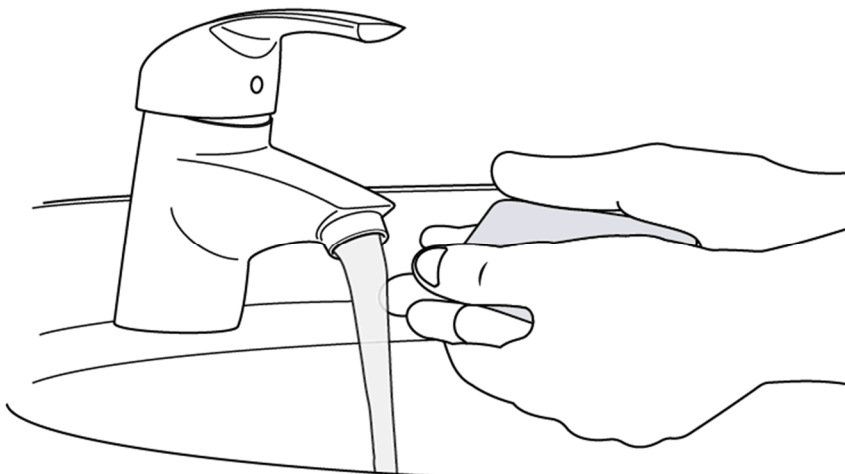


Figure F

## Step 5. Select the Injection Site

- Inject into the **thigh or belly (abdomen) area**, but stay 2 cm away from the belly button (navel) (see **Figure G**)
- If somebody else (caregiver) gives you the injection, they can also use the upper arm. **Do not** try to inject into the upper arm yourself.
- Change (rotate) your injection site with each injection. **Do not inject** in the same place multiple times if the skin is damaged.
- **Do not** inject into the belly button, moles, scars or bruises, or into areas where the skin is tender, red, hard, or injured.

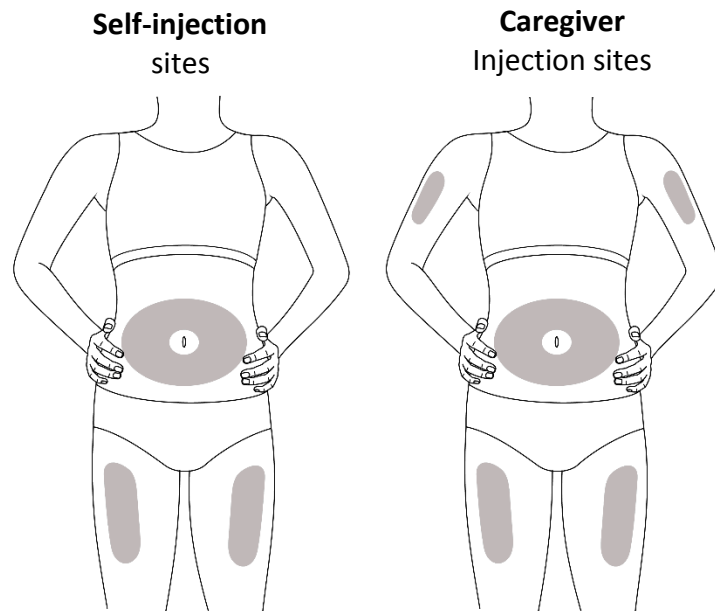


Figure G

## Step 6. Prepare the Injection Site

- Clean the injection site with an alcohol pad (see **Figure H**).
- Let your skin dry on its own.
- **Do not** touch this area again before injecting.
- **Do not** fan or blow on the skin area that you cleaned.

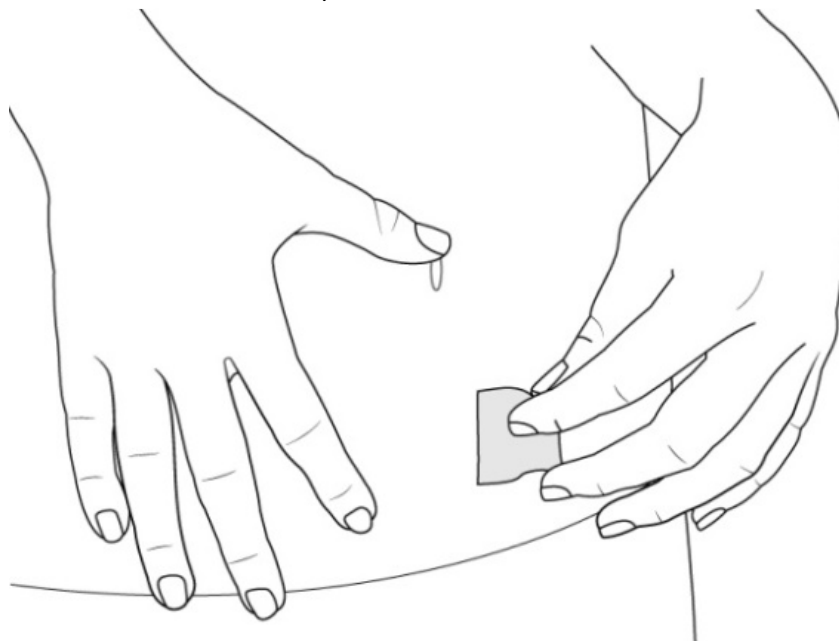


Figure H

## Injecting the Medicine with the Pre-filled Pen

Complete the Injection without stopping. Read all steps first before beginning.

Do not remove the Clear Cap until you are ready to inject.

### Step 7. Remove Clear Pre-filled Pen Cap and Dispose of the Cap

- Hold the pre-filled pen with one hand and **pull the Clear Pre-filled Pen Cap straight off** with the other hand.
- **Do not** twist the Clear Cap, (see **Figure I**). If you cannot remove the Clear Cap, ask a caregiver for help or contact your healthcare provider.
- The Clear Cap has a metal part inside, this is normal.
- **Do not put the Clear Cap back on** after it has been removed, because this could start the injection and cause injury.
- Dispose of the Clear Cap in a sharps container or closed puncture-resistant container.

#### Important:

- **Do not touch the grey needle shield of the pre-filled pen to avoid injury.**
- **Do not** put the pre-filled pen down after removing the Clear Cap.

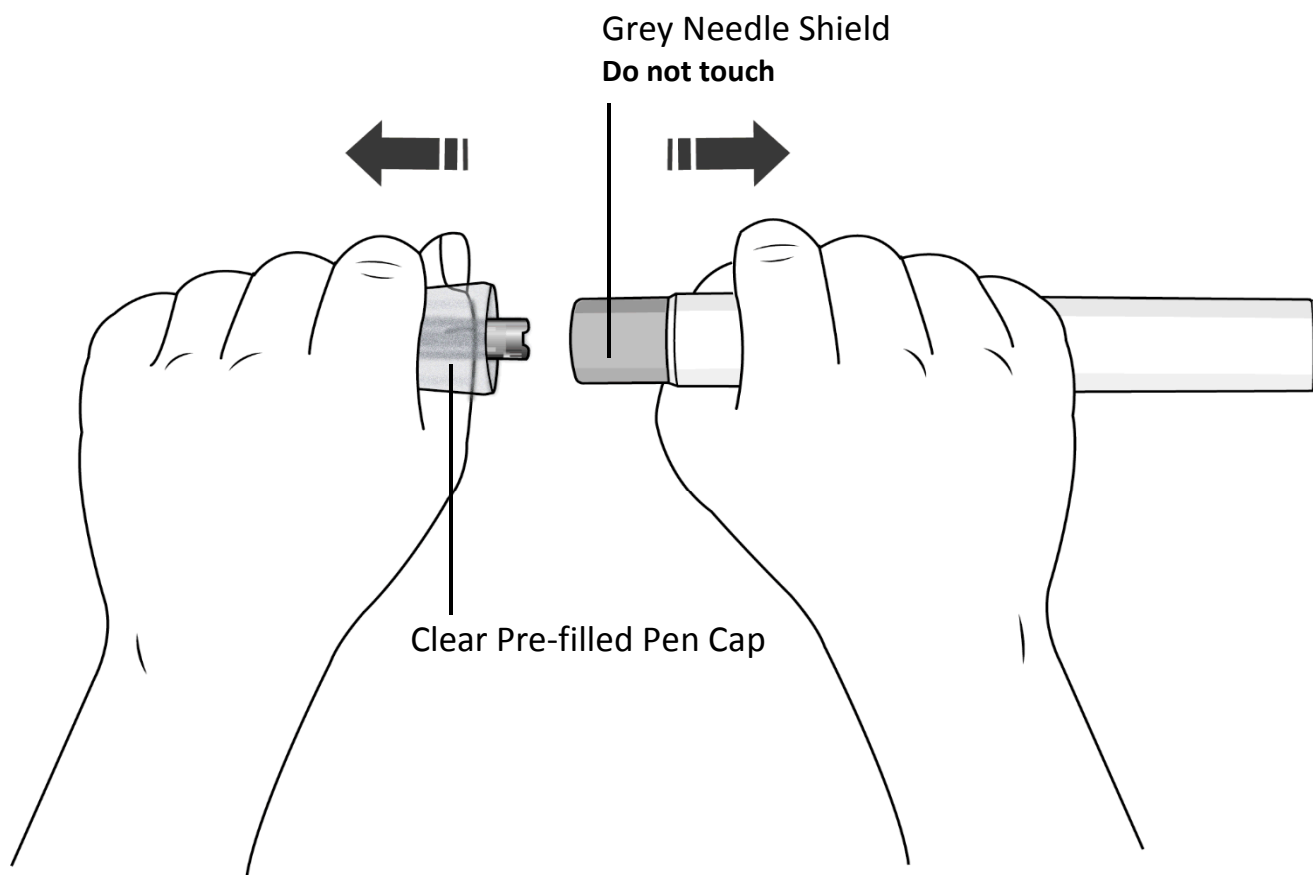


Figure I

### Step 8. Pinch the Skin and place the Pre-filled Pen on the injection site

Immediately after removing the clear pre-filled pen cap, complete the following steps without stopping:

- **Gently pinch** the area of cleaned skin around the injection site and hold the area firmly until the injection is complete (see **Figure J**).
- Place the pre-filled pen at a 90° angle on the cleaned injection site (see **Figure J**).
- **Make sure you can see the viewing window.**

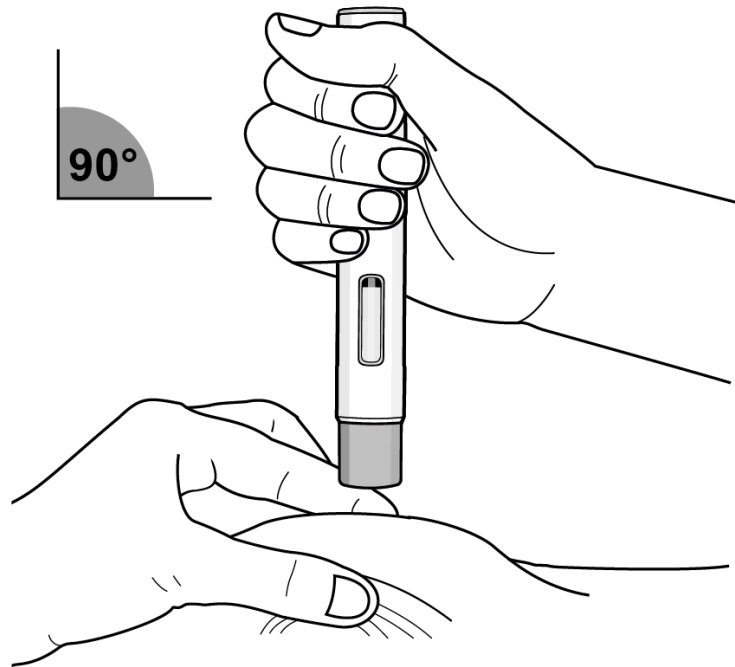


Figure J

**Step 9. Inject Medicine** (see Figure K)



**You Must Read all of Step 9 before injecting.**  
**The injection may take up to 15 seconds.**

**To ensure you receive a full dose you must keep the pre-filled pen firmly pressed against your pinched skin until:**

- **The yellow plunger has stopped moving and filled the viewing window, and**
- **5 seconds has passed after the 2<sup>nd</sup> 'Click'.**

Press the grey needle shield down firmly against the pinched skin to start the injection and keep pressing down until all the steps below are complete.

Press down to start	Keep pressing down	Keep pressing down for 5 more seconds ...1...2...3...4...5
<p><b>Press down to start</b> the injection and listen for a <b>First 'Click'</b>.</p> <ul style="list-style-type: none"> <li>• The First 'Click' means the injection has started.</li> <li>• The yellow plunger will start moving in the viewing window.</li> </ul> <p><b>Keep pressing</b> the pre-filled pen down.</p>	<p><b>Keep pressing</b> the pre-filled pen down and <b>watch the viewing window.</b></p> <ul style="list-style-type: none"> <li>• The window will turn yellow and</li> <li>• You will hear a <b>Second 'Click'</b>.</li> </ul> <p><b>Keep pressing</b> the pre-filled pen down.</p>	<p><b>Keep pressing</b> the pre-filled pen <b>down</b> for <b>5 more seconds</b> to make sure you get the full dose.</p>

**Figure K**

- **Do not** remove the pre-filled pen until the yellow plunger has stopped moving and completely filled the viewing window, and 5 seconds has passed after the Second 'Click'.
- **Do not remove, tilt, or rotate the pre-filled pen during the injection.**

### Step 10. Release the Pinch and Remove the Pre-filled Pen

- Release the pinch and remove the pre-filled pen at a 90° angle from the skin (see **Figure L**).
- As the pre-filled pen is lifted from the skin, the grey needle shield returns to the original (before use) position, and will lock into place, covering the needle.

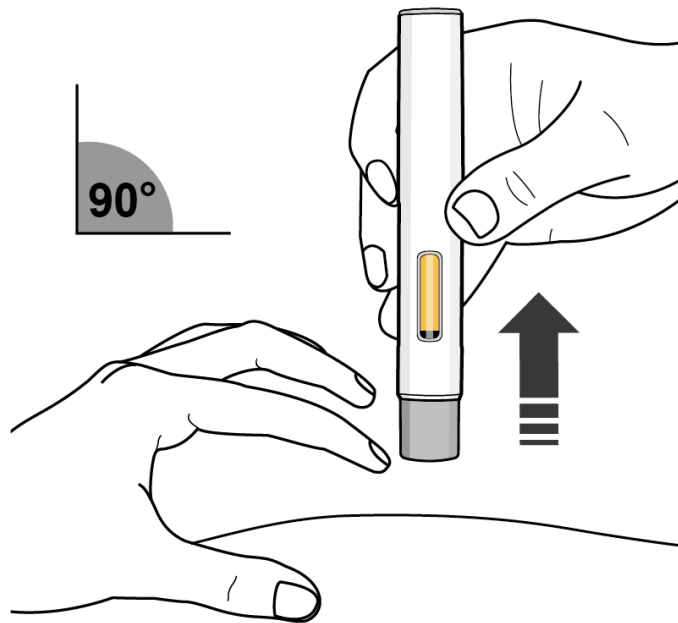


Figure L

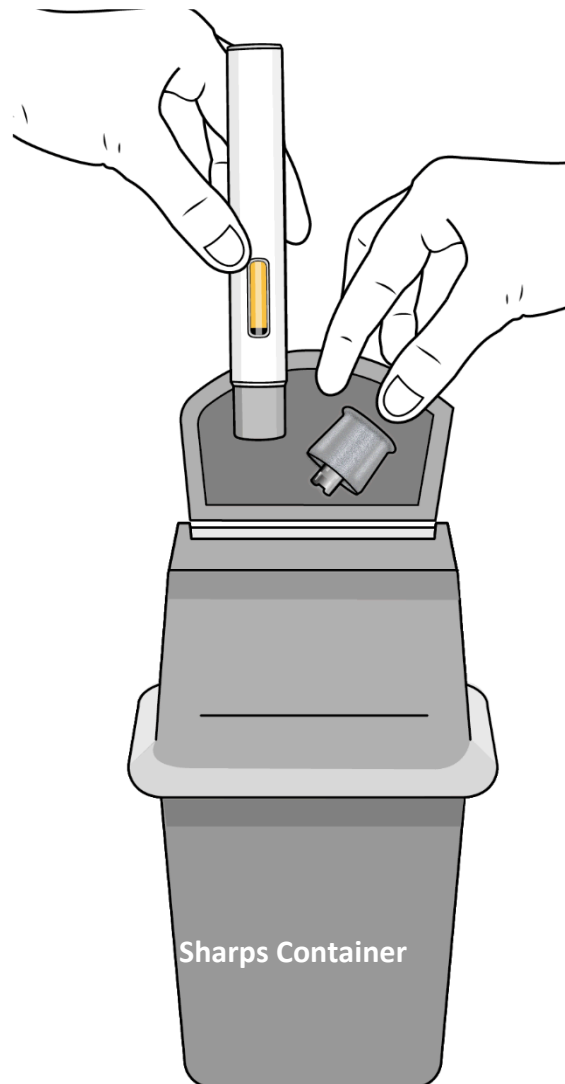
**Important: If you think that you have not received the full dose contact your healthcare provider right away.**

- If there is a little bleeding at the injection site, you can press a cotton ball or gauze over the injection site.
- **Do not** rub the injection site.
- If needed, you may cover the injection site with a small adhesive bandage.

## Disposal

### Step 11. Disposing of the Pre-filled Pen

- **Do not** try to reuse the pre-filled pen.
- After injecting your dose, put the pre-filled pen into a sharps container or closed puncture-resistant container (see **Figure M**).



**Figure M**

- If you do not have a sharps container or closed puncture resistant container, you may use a household container that is:
  - Made of heavy-duty plastic
  - Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
  - Upright stable during use
  - Leak-resistant
  - Properly labelled to warn of hazardous waste inside the container
- When your sharps container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps container.
- **Do not** dispose of your used sharps container in your household waste unless your local guidelines permit this.
- **Do not** recycle your used sharps container.

### Step 12. Keep Track of Your Treatment

- If required by your doctor, record your injection in a diary to help keep track of your medicine.