

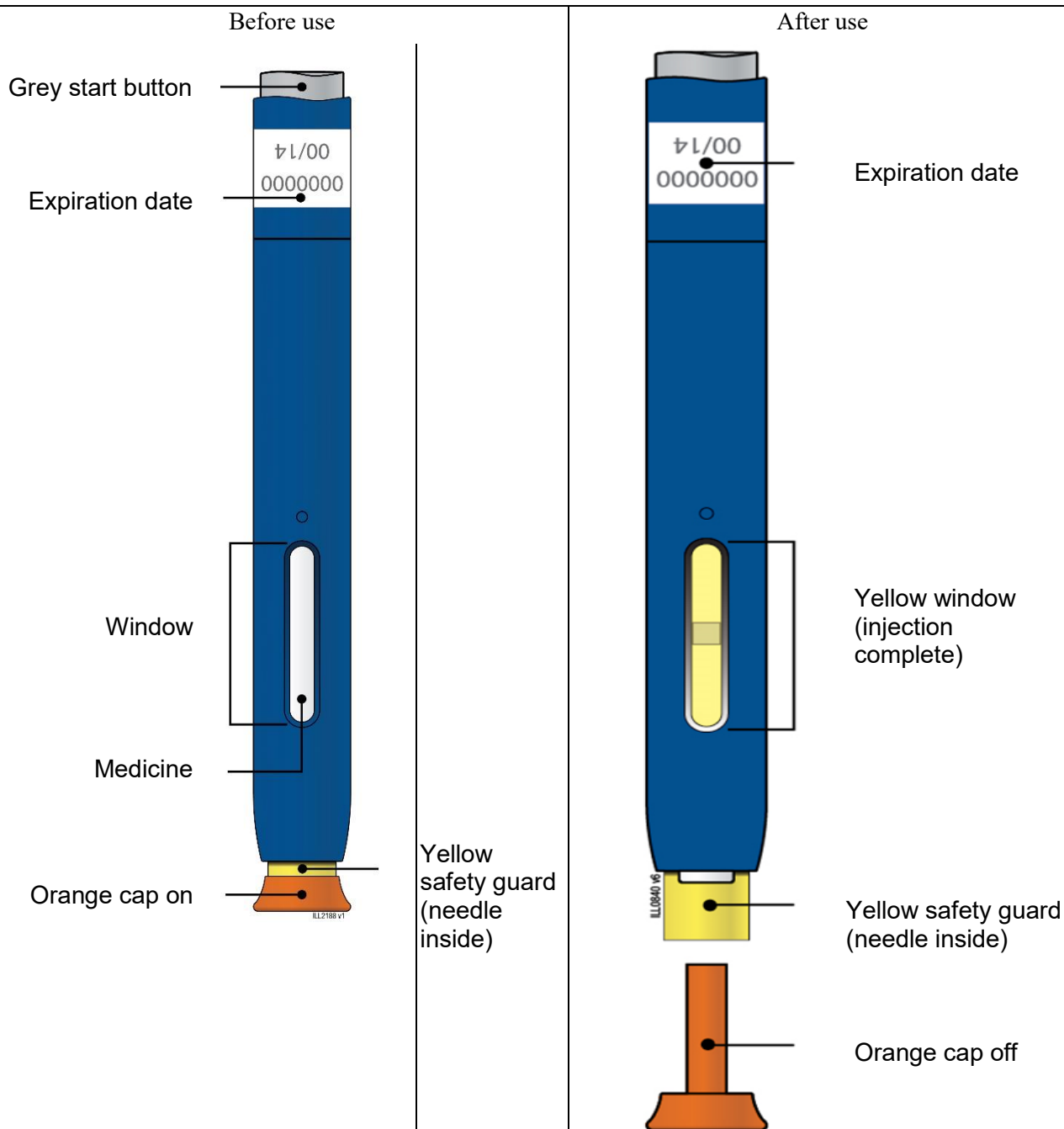
Read these instructions before using REPATHA®

Instructions for use:

Repatha® (ri-Path-a) (evolocumab)

Single-use SureClick® pre-filled pen

Guide to parts



Important: Needle is inside the yellow safety guard

Important

Before you use the Repatha pre-filled pen, read this important information:

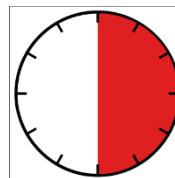
- Keep the Repatha pre-filled pen in original carton to protect from light.
- The Repatha pre-filled pen should be stored in the refrigerator (2°C to 8°C).
- It is important that you do not try to give yourself the injection unless you have received training from your healthcare provider.
- The orange cap on a Repatha pre-filled pen contains a needle cover (located inside the cap) that is composed of dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.
- Keep the Repatha pre-filled pen out of the sight and reach of children.
- **Do not** freeze or use the Repatha pre-filled pen if it has been frozen.
- **Do not** shake the Repatha pre-filled pen.
- **Do not** remove the orange cap from the Repatha pre-filled pen until you are ready to inject.
- **Do not** use the Repatha pre-filled pen if it has been dropped on a hard surface. Part of the Repatha pre-filled pen may be broken even if you cannot see the break. Use a new Repatha pre-filled pen, and contact your healthcare provider.
- **Do not** use the Repatha pre-filled pen after the expiration date.

For more information or help, call Amgen Medical Information on 1800 803 638. If required, you will be advised to contact your healthcare provider.

Step 1: Prepare

A Remove one Repatha pre-filled pen from the carton.

1. Carefully lift the pre-filled pen straight up out of the carton.
2. Put the original carton with any unused pre-filled pens back in the refrigerator.
3. Wait at least 30 minutes for the pre-filled pen to naturally reach room temperature before injecting.
 - **Do not** try to warm the pre-filled pen by using a heat source such as hot water or microwave.
 - **Do not** leave the pre-filled pen in direct sunlight.
 - **Do not** shake the pre-filled pen.
 - **Do not** remove the orange cap from the pre-filled pen yet.



30 minutes

B	Inspect the Repatha pre-filled pen.
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Make sure the medicine in the window is clear and colourless to slightly yellow.

Check the expiration date.

- **Do not** use the pre-filled pen if medicine is cloudy or discoloured or contains large lumps, flakes, or particles.
- **Do not** use the pre-filled pen if any part appears cracked or broken.
- **Do not** use the pre-filled pen if the pre-filled pen has been dropped.
- **Do not** use the pre-filled pen if the orange cap is missing or not securely attached.
- **Do not** use the pre-filled pen if the expiration date has passed.

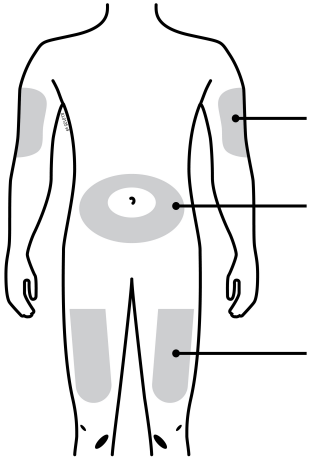
In all cases, call Amgen Medical Information on 1800 803 638. If required, you will be advised to contact your healthcare provider and use a new pre-filled pen.

C	Gather all materials needed for your injection.
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Wash your hands thoroughly with soap and water.

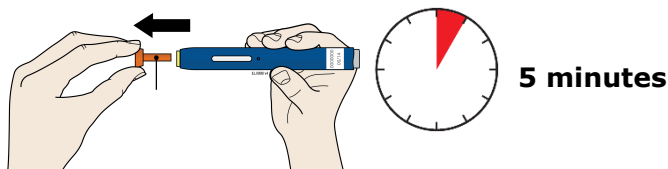
On a clean, well-lit work surface, place the:

- New pre-filled pen.
- Alcohol wipes.
- Cotton ball or gauze pad.
- Adhesive bandage.
- Sharps disposal container (see Step 4: Finish).

D	Prepare and clean your injection site.
Only use these injection sites: • Thigh. • Stomach area (abdomen), except for a two inch (five centimetre) area around your belly button. • Outer area of upper arm (only if someone else is giving you the injection). Clean the injection site with an alcohol wipe. Let your skin dry. • Do not touch this area again before injecting. • Choose a different site each time you give yourself an injection. If you need to use the same injection site, just make sure it is not the same spot on that site you used last time. • Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.	
 Upper arm Stomach area (abdomen) Thigh	

Step 2: Get ready

- A** Pull the orange cap straight off only when you are ready to inject. **Do not** leave the orange cap off for more than five minutes. This can dry out the medicine.



Orange cap

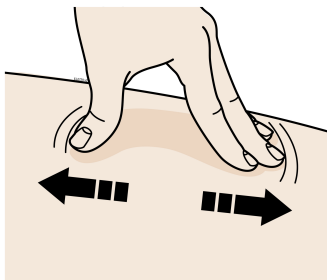
It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

- **Do not** twist, bend or wiggle the orange cap.
- **Do not** put the orange cap back onto the pre-filled pen.
- **Do not** put fingers into the yellow safety guard.
- **Do not** remove the orange cap from the pre-filled pen until you are ready to inject.

If you are unable to inject, please call Amgen Medical Information on 1800 803 638. If required, you will be advised to contact your healthcare provider.

- B** Create a firm surface at the selected injection site (thigh, stomach, or outer areas of the upper arm), by using **either** the Stretch method **or** the Pinch method.

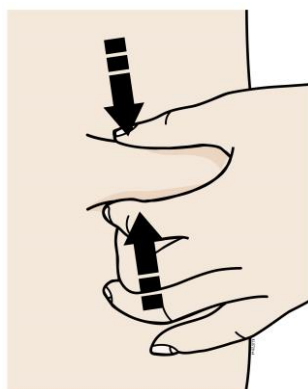
Stretch method



Stretch the skin firmly by moving your thumb and fingers in the opposite direction, creating an area about two inches (five centimetres) wide.

or

Pinch method

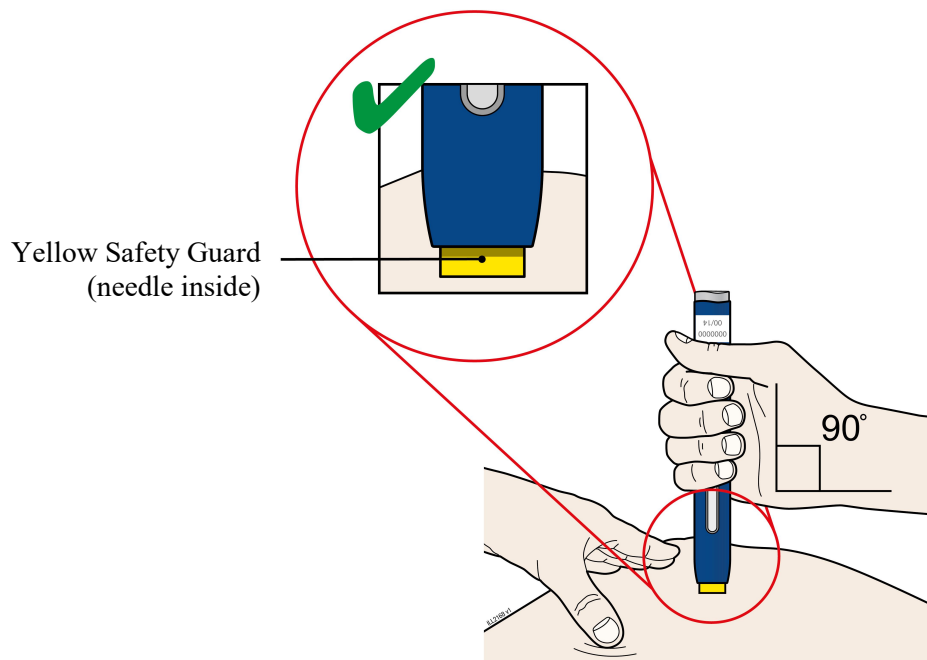


Pinch the skin firmly between your thumb and fingers, creating an area about two inches (five centimetres) wide.

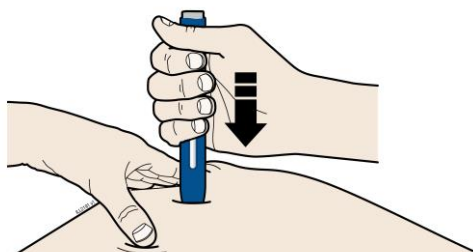
Important: It is important to keep skin stretched or pinched while injecting.

Step 3: Inject

- A** Keep holding the stretched or pinched skin. With the orange cap off, **put** the yellow safety guard on your skin at 90 degrees. The **needle is inside** the yellow safety guard. Do not touch the grey start button yet.



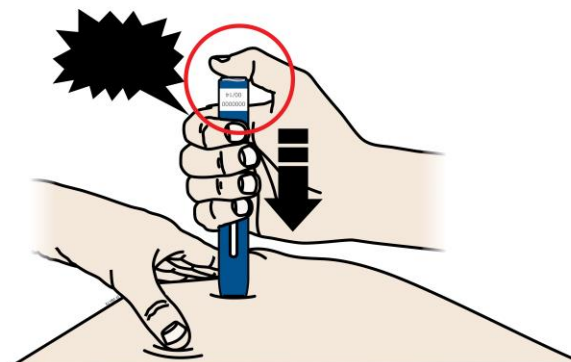
- B** Firmly **push** down the pre-filled pen onto the skin until the yellow safety guard is fully retracted and stops moving.

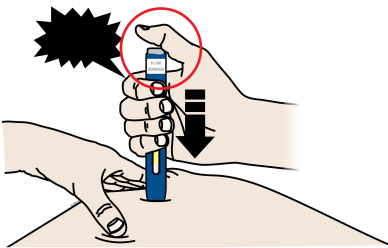
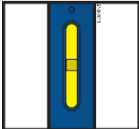
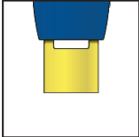


Important: You must push the yellow safety guard all the way down to unlock the activation mechanism but **do not** touch the grey start button until you are ready to inject.

- C** When you are ready to inject, **press** the grey start button. You will hear a click.

"click"



D	Keep pushing down on the skin to make sure the yellow safety guard remains retracted whilst the dose is administered. Then lift your thumb while still holding the pre-filled pen on your skin. Your injection could take about 15 seconds. Check the window has turned yellow before removing the pre-filled pen.
“click”   15 seconds  Window turns from clear to yellow when the injection is done. You may hear a second click.  NOTE: After you remove the pre-filled pen from your skin, the needle will be automatically covered.	

Step 4: Finish	
A	Discard the used pre-filled pen and orange needle cap.
 Discard the used pre-filled pen and the orange cap in a sharps disposal container. Talk with your healthcare provider about proper disposal. There may be local guidelines for disposal. Keep the pre-filled pen and the sharps disposal container out of the sight and reach of children. ● Do not reuse the pre-filled pen. ● Do not recap the pre-filled pen or put fingers into the yellow safety guard. ● Do not recycle the pre-filled pen or sharps disposal container or throw them into household rubbish.	
B	Examine the injection site.
If there is blood, press a cotton ball or gauze pad on your injection site. Do not rub the injection site. Apply an adhesive bandage if needed.	

Commonly Asked Questions

What will happen if I press the grey start button before I am ready to do the injection on my skin?

You can lift your finger up off the grey start button and place the pre-filled pen back on your injection site. Then, you can push the grey start button again.

Can I move the pre-filled pen around on my skin while I am choosing an injection site?

It is okay to move the pre-filled pen around on the injection site as long as you do not press the grey start button. However, if you press the grey start button and the yellow safety guard is pushed into the pre-filled pen, the injection will begin.

Can I release the grey start button after I start my injection?

You can release the grey start button, but continue to hold the pre-filled pen firmly against your skin during the injection.

Will the grey start button pop up after I release my thumb?

The grey start button may not pop up after you release your thumb if you held your thumb down during the injection. This is okay.

What do I do if I did not hear a second click?

If you did not hear a second click, you can confirm a complete injection by checking that the window has turned yellow.

Whom do I contact if I need help with the pre-filled pen or my injection?

For more information or help, call Amgen Medical Information on 1800 803 638. If required, you will be advised to contact your healthcare provider.

Repatha[®] is a trademark of Amgen.
Amgen Australia Pty Ltd.
Level 11, 10 Carrington Rd, Sydney, NSW 2000

Date of last amendment: 8 June 2022

Ph: 1800 803 638

SYMBOL TABLE

 This Product Contains Dry Natural Rubber	 Single use	 CAUTION, Consult Accompanying Documents	 140 mg/mL Pre- filled pen	 Lot number
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Front Panel Text

Read these instructions before using REPATHA®
Single-Use SureClick® Pre-filled Pen