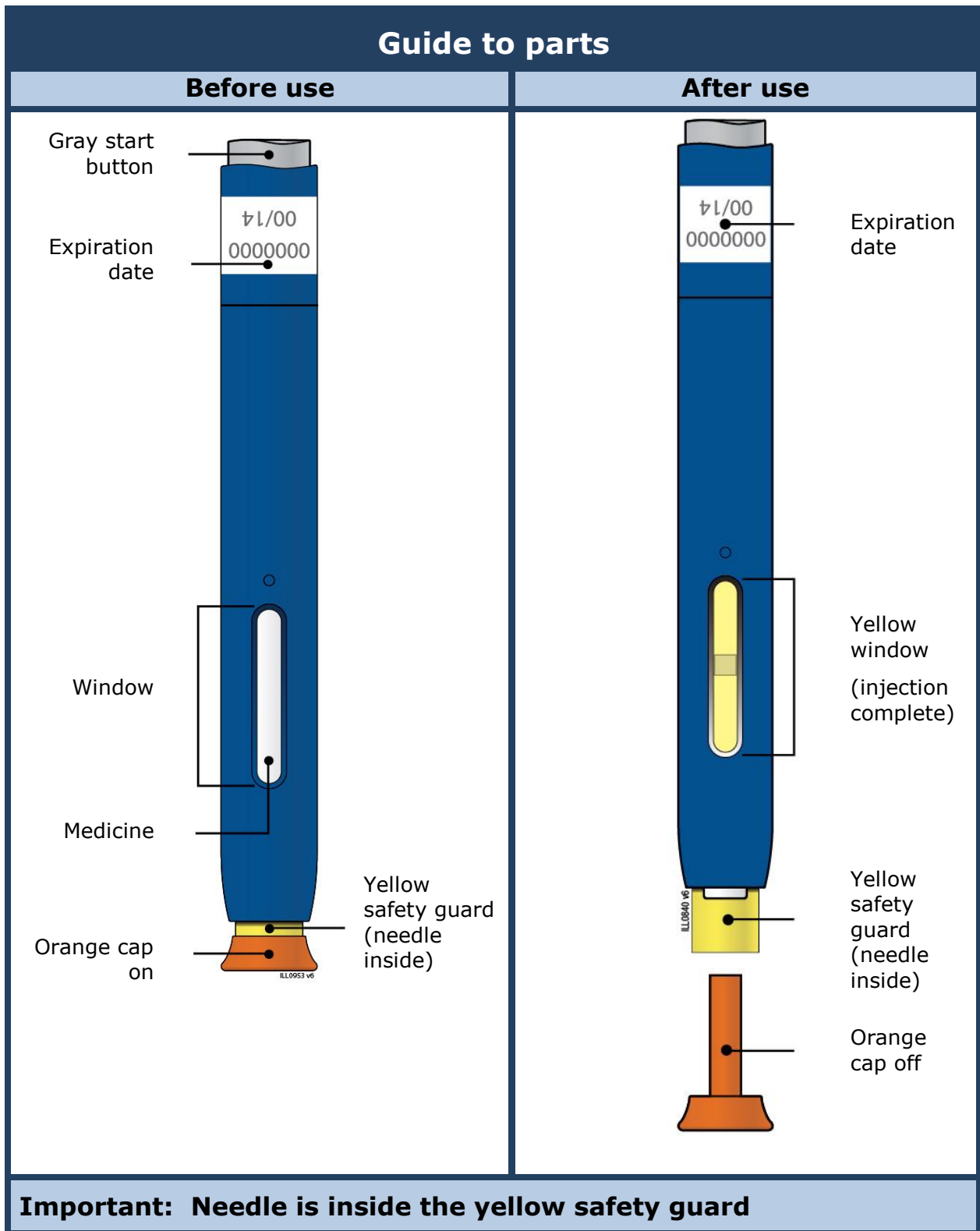


**Instructions for Use**  
**Repatha® (ri-PATH-a)**  
**(evolocumab)**  
**Single-Use Prefilled SureClick® Autoinjector**



## Important

### **Before you use a Single-Use Repatha SureClick autoinjector, read this important information:**

- It is important that you do not try to give yourself or someone else the injection unless you have received training from your healthcare provider.
- The orange cap on the Repatha SureClick autoinjector contains a needle cover (located inside the cap) that contains dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.

### **Storage of Repatha:**

- Keep the Repatha SureClick autoinjector in the original carton to protect from light during storage.
- Keep the Repatha SureClick autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If removed from the refrigerator, the Repatha SureClick autoinjector should be kept at room temperature at 68°F to 77°F (20°C to 25°C) in the original carton and must be used within **30** days.
- **Do not** freeze the Repatha SureClick autoinjector or use a Repatha SureClick autoinjector that has been frozen.

### **Using Repatha:**

- **Do not** shake the Repatha SureClick autoinjector.
- **Do not** remove the orange cap from the Repatha SureClick autoinjector until you are ready to inject.
- **Do not** use the Repatha SureClick autoinjector if it has been dropped on a hard surface. Part of the Repatha SureClick autoinjector may be broken even if you cannot see the break. Use a new Repatha SureClick autoinjector, and call 1-844-REPATHA (1-844-737-2842).
- **Do not** use the Repatha SureClick autoinjector after the expiration date.

A healthcare provider who knows how to use the Repatha SureClick autoinjector should be able to answer your questions. For more information, call 1-844-REPATHA (1-844-737-2842) or visit [www.REPATHA.com](http://www.REPATHA.com).

Keep the Repatha SureClick autoinjector out of the sight and reach of children.

## Step 1: Prepare

### 1A Remove 1 Repatha SureClick autoinjector from the package.

Carefully lift the autoinjector straight up out of the box.

Put the original package with any unused autoinjectors back in the refrigerator.

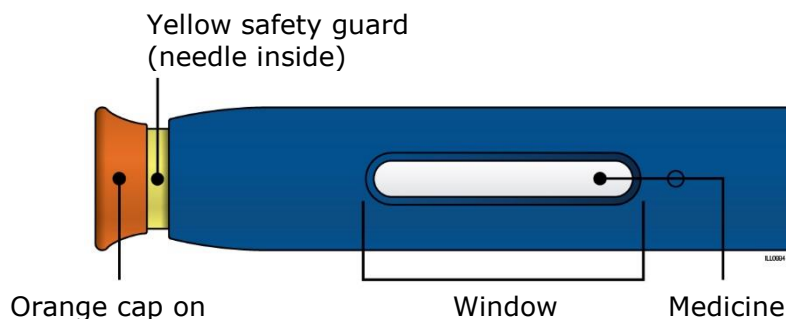
Wait at least **30 minutes** for the autoinjector to reach room temperature before injecting.

This is important for administering the entire dose and helps minimize discomfort. Repatha may take longer to inject if it has not reached room temperature. **Do not** heat the autoinjector. Let it warm up on its own.



- **Do not** try to warm the autoinjector by using a heat source such as hot water or microwave
- **Do not** leave the autoinjector in direct sunlight
- **Do not** shake the autoinjector
- **Do not** remove the orange cap from the autoinjector yet

### 1B Inspect the Repatha SureClick autoinjector.



Check the expiration date. **Do not** use the Repatha SureClick autoinjector past the expiration date printed on the label.

**Make sure the medicine in the window is clear and colorless to slightly yellow.**

- **Do not** use the autoinjector if the medicine is cloudy or discolored or contains particles.
- **Do not** use the autoinjector if any part appears cracked or broken.
- **Do not** use the autoinjector if the autoinjector has been dropped.
- **Do not** use the autoinjector if the orange cap is missing or not securely attached.

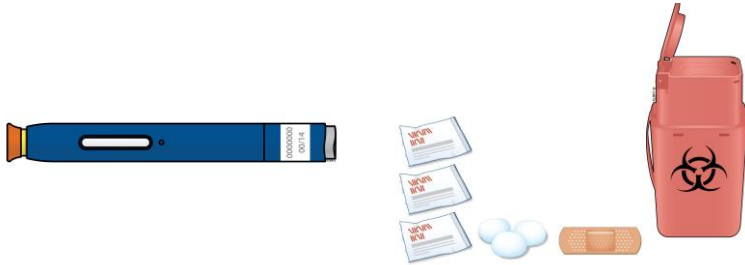
In all cases, use a new autoinjector, and call 1-844-REPATHA (1-844-737-2842).

## 1C Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water.

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

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



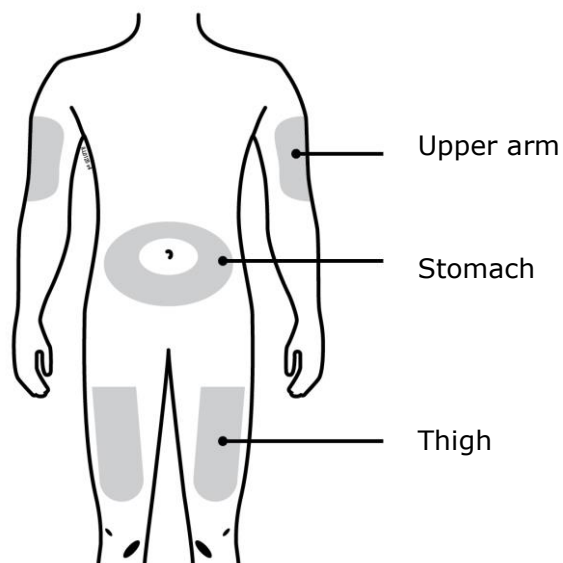
## 1D Prepare and clean your injection site.

**Only use these injection sites:**

- Thigh
- Stomach (abdomen), except for a **two** inch area around your belly button
- Outer area of upper arm (only if someone else is giving you the injection)

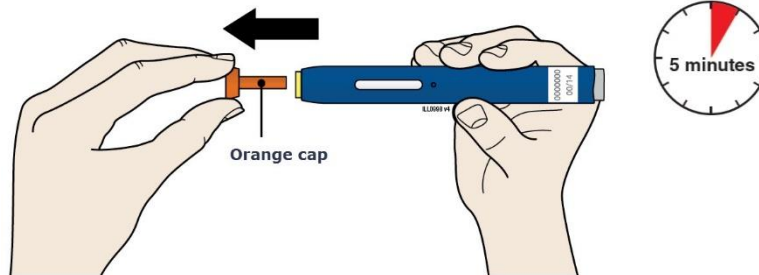
Clean your injection site with an alcohol wipe. Let your skin dry.

- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot you used for the last injection.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard.



## Step 2: Get ready

- 2A** Pull the orange cap 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.



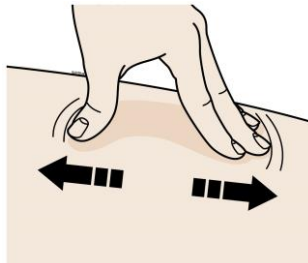
It is normal to see a drop of liquid at the end of the needle or yellow safety guard

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

If you are unable to inject, please contact your healthcare provider.

- 2B** 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.

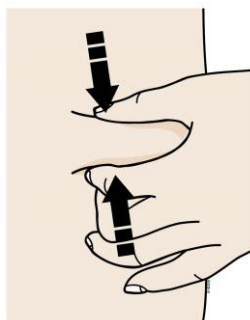
### Stretch method:



Stretch the skin firmly by moving your thumb and fingers in opposite directions, creating an area about **two** inches wide.

**or**

### Pinch method:

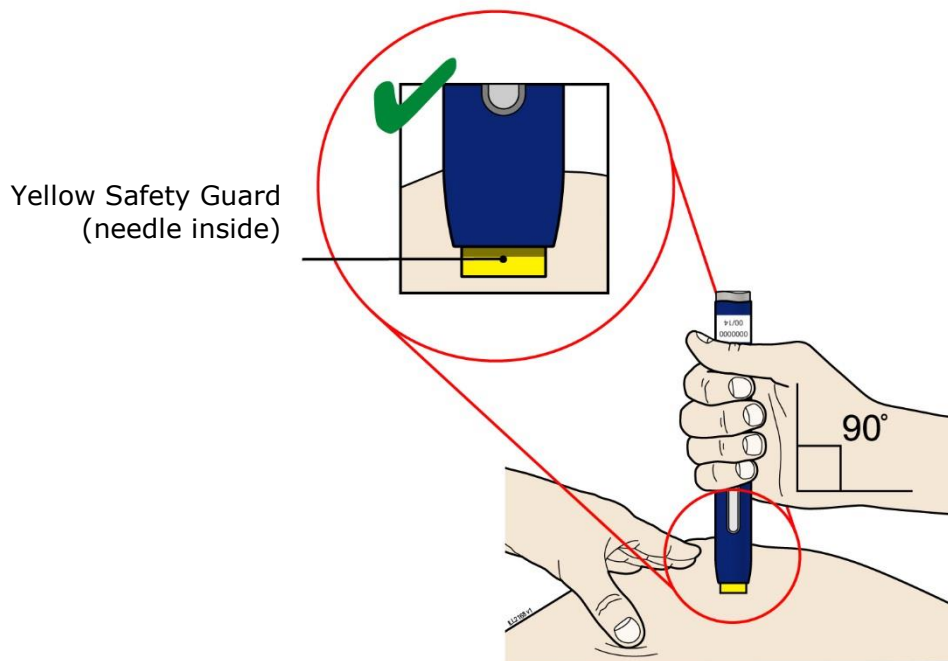


Pinch the skin firmly between your thumb and fingers, creating an area about **two** inches wide.

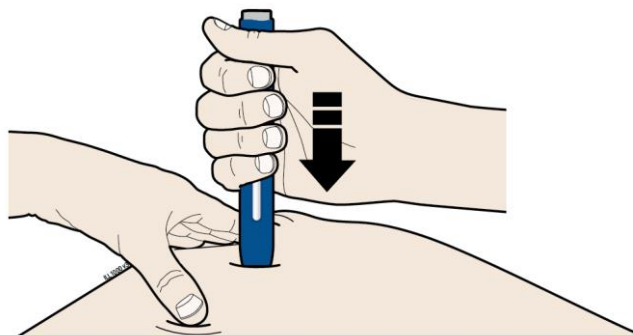
**Important:** It is important to keep skin stretched or pinched while injecting.

### Step 3: Inject

**3A** 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 gray start button yet.

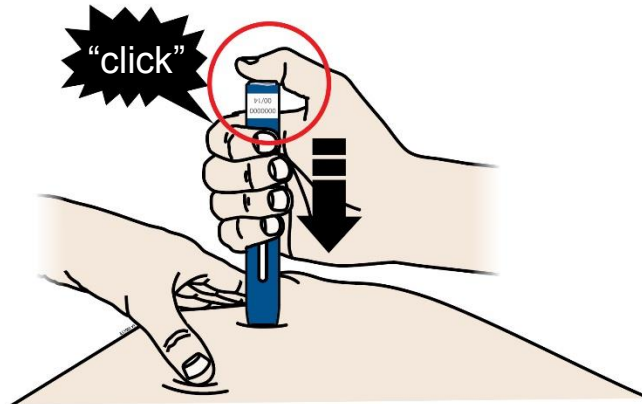


**3B** Firmly **push** down the autoinjector onto the skin until it stops moving.

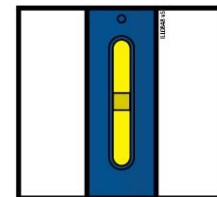
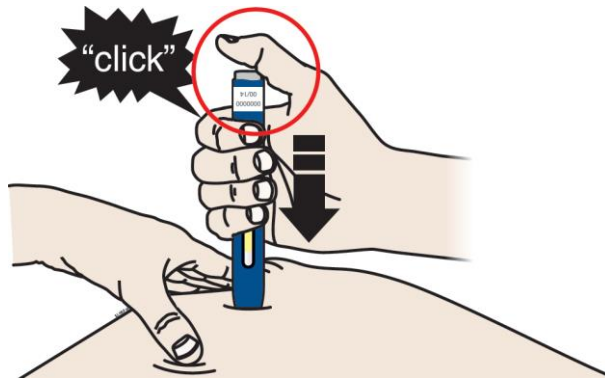


**Important:** You must push all the way down but **do not** touch the gray start button until you are ready to inject.

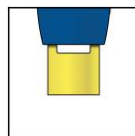
**3C** When you are ready to inject, **press** the gray start button. You will hear a click.



**3D** Keep **pushing** the autoinjector down on your skin. Then **lift** your thumb while still holding the autoinjector on your skin. Your injection could take about 15 seconds.



Window turns from clear to yellow when the injection is done. You may hear a second click.



**NOTE:** After you remove the autoinjector from your skin, the needle will be automatically covered.

**Important:** When you remove the autoinjector, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.

## Step 4: Finish

### 4A Throw away the used autoinjector and orange needle cap.



Put the used autoinjector and orange needle cap in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the autoinjector or orange cap in your household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:

<http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

- **Do not** reuse the autoinjector.
- **Do not** recap the autoinjector or put fingers into the yellow safety guard.

**Important:** Always keep the sharps disposal container out of reach of children.

### 4B Check the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. Apply an adhesive bandage if needed.

**Do not** rub the injection site.



## Commonly Asked Questions

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

You can lift your finger up off the gray start button and place the prefilled autoinjector back on your injection site. Then, you can push the gray start button again.

### **Can I move the autoinjector around on my skin while I am choosing an injection site?**

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

### **Can I release the gray start button after I start my injection?**

You can release the gray start button, but continue to hold the autoinjector firmly against your skin during the injection.

### **Will the gray start button pop up after I release my thumb?**

The gray 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 autoinjector or my injection?**

A healthcare provider familiar with Repatha should be able to answer your questions. For more information, call 1-844-REPATHA (1-844-737-2842) or visit [www.REPATHA.com](http://www.REPATHA.com).

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

# AMGEN<sup>®</sup>

### **Manufactured by:**

Amgen Inc.

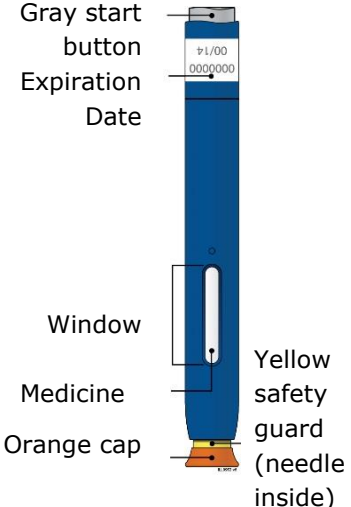
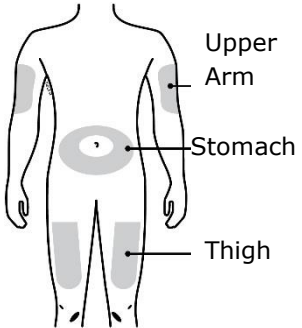
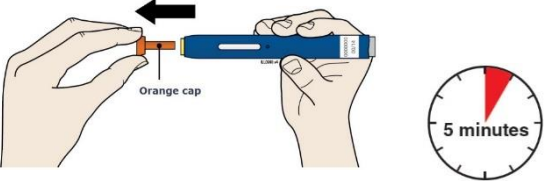
Thousand Oaks, CA 91320-1799

© 2015-2016,2018-2019 Amgen Inc.

All rights reserved.

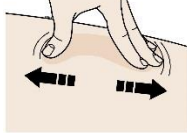
<part number> Revised: 02/2019 v5

## APPENDIX 1- REFERENCE GUIDE

<p><b>Side 1</b></p> <p>Reference Guide          Repatha® (ri-PATH-a) (evolocumab)          Single-Use          Prefilled SureClick® Autoinjector</p>		<p>Read all instructions in carton before use.</p>
<p>Guide to parts</p>  <p>Gray start button          Expiration Date          Window          Medicine          Orange cap          Yellow safety guard (needle inside)</p>	<p>Wait at least 30 minutes for the autoinjector to come to room temperature before giving your injection.</p> <p>Step 1. Prepare and clean your injection site.</p>  <p>Upper Arm          Stomach          Thigh</p>	<p>Step 2. Pull the orange cap off only when you are ready to inject. <b>Do not</b> leave the orange cap off for more than <b>5 minutes</b>. This can dry out the medicine.</p>  <p>Orange cap</p> <p>5 minutes</p> <p>Turn over to continue</p>

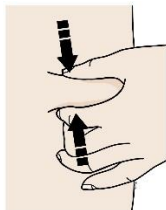
Step 3. Stretch **or** pinch your injection site to create a firm surface.

**Stretch method:**



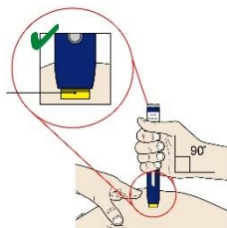
**or**

**Pinch method:**



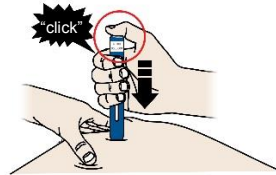
Step 4. **Put** the yellow safety guard (needle inside) on your skin at 90 degrees.

Yellow safety guard (needle inside)

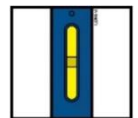


Step 5. Firmly push down the autoinjector onto your skin until it stops moving.

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



Step 6. Keep **pushing** down on your skin for about 15 seconds.



Window turns from clear to yellow when the injection is done.

