

Patient Information
REPATHA[®] (ri-PAth-a)
(evolocumab)
injection, for subcutaneous use

What is REPATHA?

REPATHA is an injectable prescription medicine used:

- in adults with cardiovascular disease to reduce the risk of heart attack, stroke, and certain types of heart surgery.
- along with diet alone or together with other cholesterol-lowering medicines in adults with high blood cholesterol levels called primary hyperlipidemia (including a type of high cholesterol called heterozygous familial hypercholesterolemia) to reduce low density lipoprotein (LDL) or bad cholesterol.
- along with diet and other LDL-lowering medicine in people with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH), who need additional lowering of LDL cholesterol.

It is not known if REPATHA is safe and effective in children with HoFH who are younger than 13 years of age or in children who do not have HoFH.

Who should not use REPATHA?

Do not use REPATHA if you are allergic to evolocumab or to any of the ingredients in REPATHA. See the end of this leaflet for a complete list of ingredients in REPATHA.

What should I tell my healthcare provider before using REPATHA?

Before you start using REPATHA, tell your healthcare provider about all your medical conditions, including if you:

- are allergic to rubber or latex. The needle covers on the single-use prefilled syringes and within the needle caps on the single-use prefilled SureClick[®] autoinjectors contain dry natural rubber. The single-use Pushtonex[®] system (on-body infusor with prefilled cartridge) is not made with natural rubber latex.
- are pregnant or plan to become pregnant. It is not known if REPATHA will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking REPATHA.

Pregnancy Registry. There is a pregnancy registry for women who take REPATHA during pregnancy. The purpose of this registry is to collect information about your health and your baby's health. You can talk to your healthcare provider or contact 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/repatha/> to enroll in this registry or get more information.

- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take REPATHA or breastfeed.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines, vitamins, or herbal supplements you take.

How should I use REPATHA?

- **See the detailed “Instructions for Use” that comes with this patient information about the right way to prepare and give REPATHA.**
- Use REPATHA exactly as your healthcare provider tells you to use it.
- REPATHA is given under the skin (subcutaneously), every 2 weeks or 1 time each month.
- REPATHA comes as a single-use (1 time) prefilled autoinjector (SureClick[®] autoinjector), as a single-use prefilled syringe or as a single-use Pushtonex[®] system (on-body infusor with prefilled cartridge). Your healthcare provider will prescribe the type and dose that is best for you.
- If your healthcare provider prescribes you the monthly dose, you may use:
 - a single-use on-body infusor with prefilled cartridge to give the injection over 9 minutes, or
 - 3 separate injections in a row, using a different single-use prefilled syringe or single-use prefilled autoinjector for each injection. Give all of these injections within 30 minutes.
- If your healthcare provider decides that you or a caregiver can give REPATHA, you or your caregiver should receive training on the right way to prepare and inject REPATHA. **Do not** try to inject REPATHA until you have been shown the right way by your healthcare provider or nurse.
 - If you are using the prefilled autoinjector, put the **yellow safety guard (needle inside) of the SureClick autoinjector on the skin before injecting.**
- **Do not** inject REPATHA together with other injectable medicines at the same injection site.
- Always check the label of your single-use prefilled autoinjector, single-use prefilled syringe, or single-use on-body infusor with prefilled cartridge to make sure you have the correct medicine and the correct dose of REPATHA before

each injection.

- If you forget to use REPATHA or are not able to take the dose at the regular time, inject your missed dose as soon as you remember, as long as it is within 7 days of the missed dose.
 - If it is more than 7 days from the missed dose and you are using the every-2-week dose, inject the next dose based on your original schedule. This will put you back on your original schedule.
 - If it is more than 7 days from the missed dose and you are using the 1 time each-month dose, inject the dose and start a new schedule using this date.

If you are not sure when to take REPATHA after a missed dose, ask your healthcare provider or pharmacist.

- If your healthcare provider has prescribed REPATHA along with other cholesterol-lowering medicines, follow instructions from your healthcare provider. Read the patient information for those medicines.
- If you use more REPATHA than you should, talk to your healthcare provider or pharmacist.
- **Do not** stop using REPATHA without talking with your healthcare provider. If you stop using REPATHA, your cholesterol levels can increase.

What are possible side effects of REPATHA?

REPATHA can cause serious side effects including:

- **Serious allergic reactions.** Some people taking REPATHA have had serious allergic reactions. Stop taking REPATHA and call your healthcare provider or seek emergency medical help right away if you have any of these symptoms:
 - trouble breathing or swallowing
 - raised bumps (hives)
 - rash, or itching
 - swelling of the face, lips, tongue, throat or arms

The most common side effects of REPATHA include: runny nose, sore throat, symptoms of the common cold, flu or flu-like symptoms, back pain, high blood sugar levels (diabetes) and redness, pain, or bruising at the injection site.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of REPATHA. Ask your healthcare provider or pharmacist for more information.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of REPATHA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use REPATHA for a condition for which it was not prescribed. **Do not** give REPATHA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about REPATHA that is written for healthcare professionals.

What are the ingredients in REPATHA?

- Active Ingredient: evolocumab
- Inactive Ingredients: proline, glacial acetic acid, polysorbate 80, water for injection, and sodium hydroxide.

Manufactured by: Amgen Inc. One Amgen Center Drive, Thousand Oaks, California 91320-1799.

U.S. License Number 1080

Patent: <http://pat.amgen.com/repatha/>

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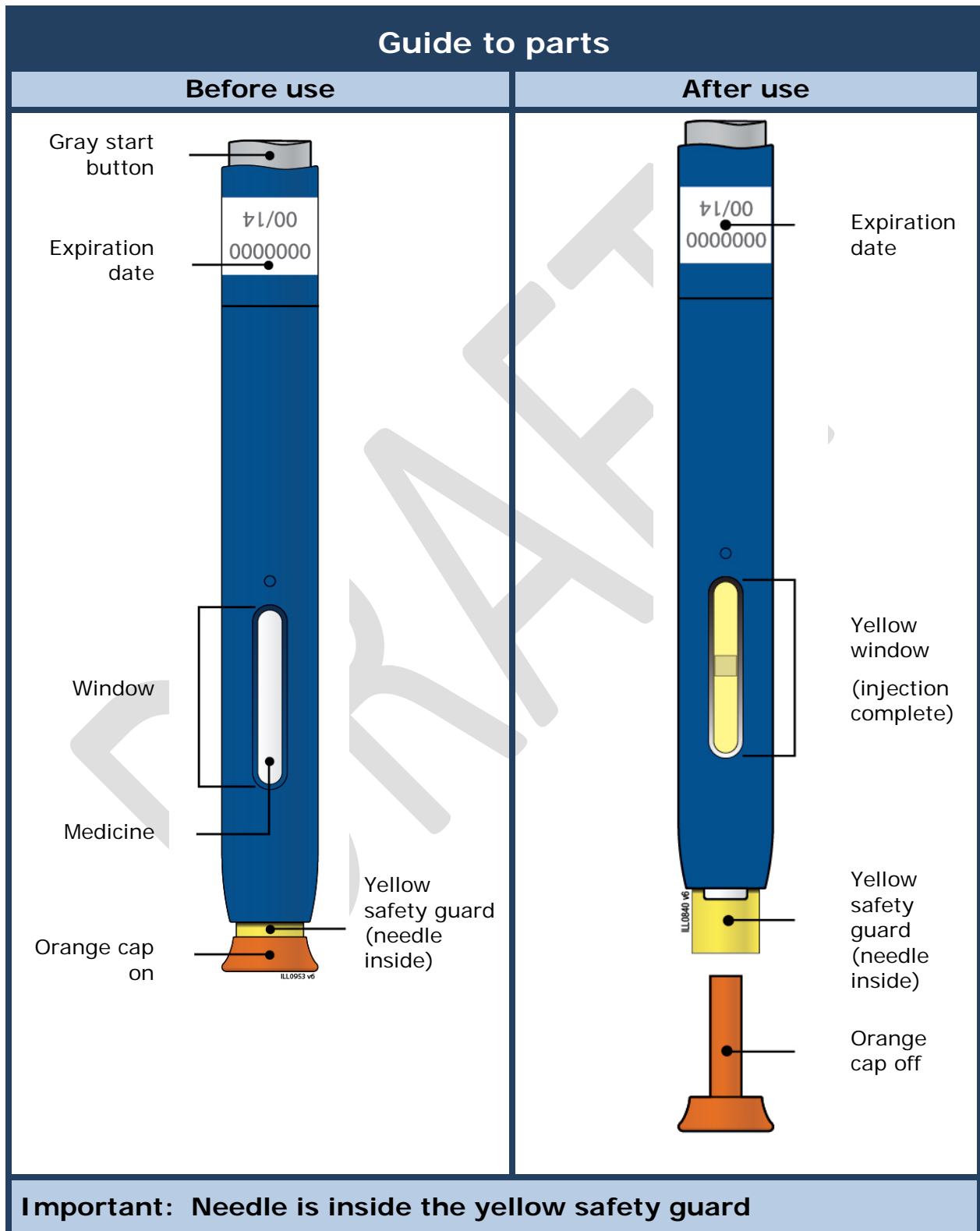
For more information about REPATHA, go to www.REPATHA.com or call 1-844-REPATHA (1-844-737-2842).

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 02/2019

V5

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.

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.

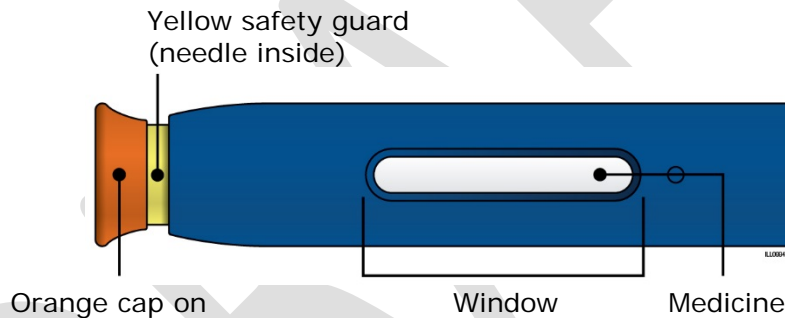
Wait at least **30 minutes** for the autoinjector to reach room temperature before injecting.

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)



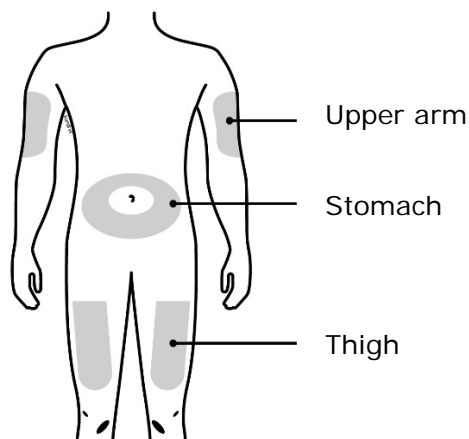
1D Prepare and clean your injection site.

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)

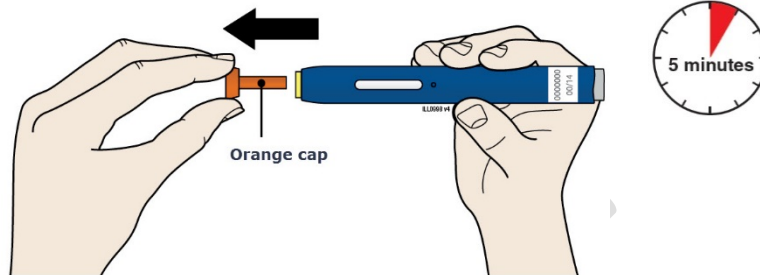
Clean your injection site with an alcohol wipe. Let your skin dry.

- **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.



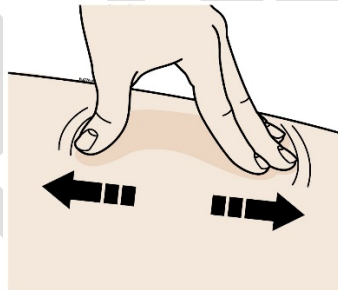
It is normal to see a drop of liquid at the end of the needle or yellow safety guard

- **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.

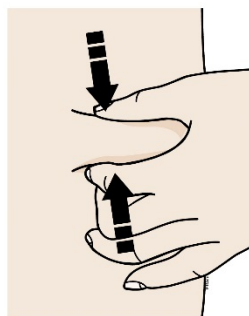
Stretch method:



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

or

Pinch method:

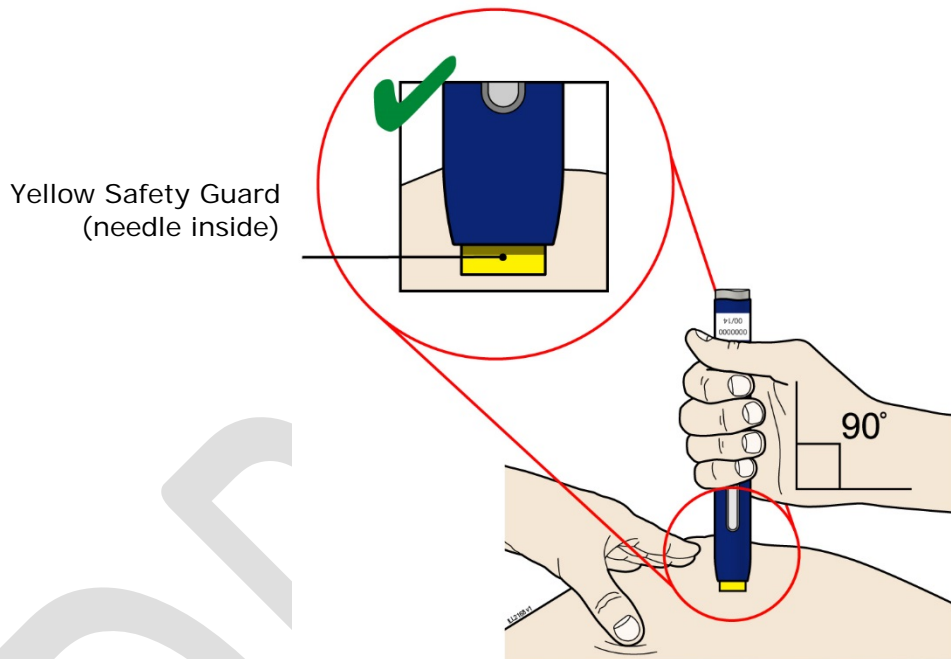


Pinch the skin firmly between your thumb and fingers, creating an area about **two** inches wide.

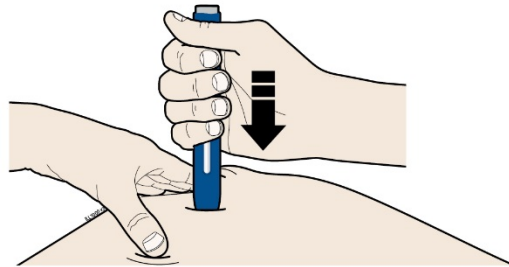
Important: It is important to keep skin stretched or pinched while injecting.

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.

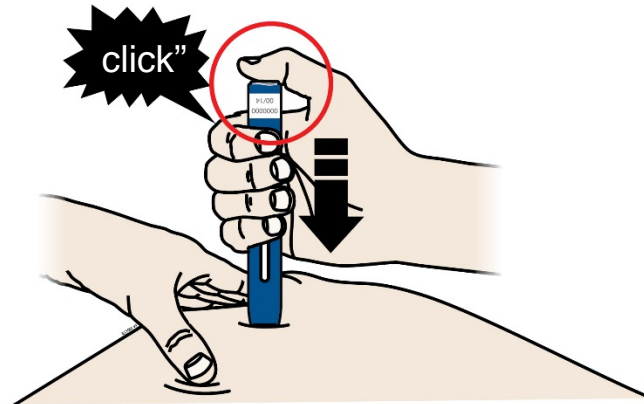


- 3B** Firmly **push** down the autoinjector onto the skin until it stops moving.

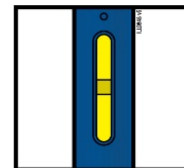
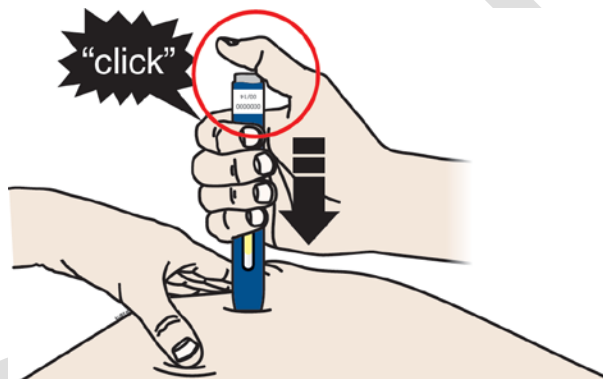


Important: You must push all the way down but **do not** touch the gray start button until you are ready to inject.

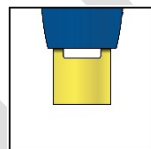
3C When you are ready to inject, **press** the gray start button. You will hear a click.



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?

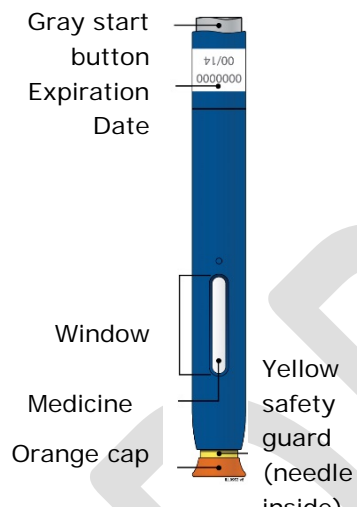
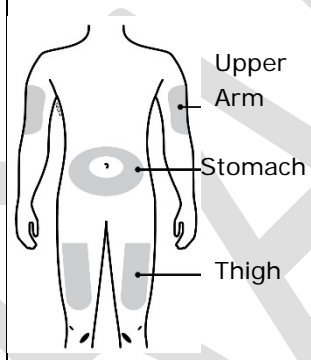
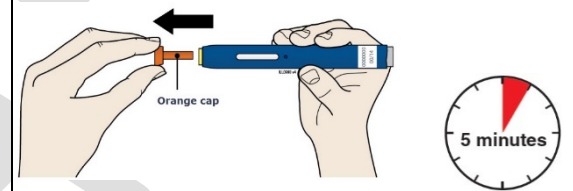
A healthcare provider familiar with Repatha should be able to answer your questions. For more information, call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

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

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<part number> Revised:

APPENDIX 1- REFERENCE GUIDE

<p>Side 1 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>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>Step 2. Pull the orange cap off only when you are ready to inject. Do not leave the orange cap off for more than 5 minutes. This can dry out the medicine.</p>  <p style="text-align: right;">Turn over to continue</p>

Side 2

Reference
Guide

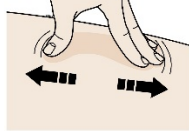


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**Read other side
first**

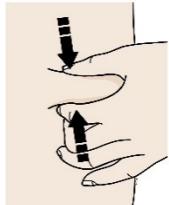
Step 3. Stretch **or** pinch your injection site to create a firm surface.

Stretch method:



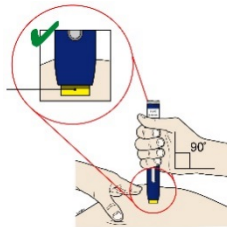
or

Pinch method:



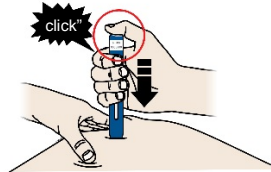
Step 4. **Put** the yellow safety guard (needle inside) on your skin at 90 degrees.

Yellow safety guard (needle inside)

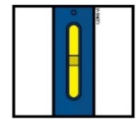


Step 5. Firmly push down the autoinjector onto your skin until it stops moving.

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.

