INSTRUCTIONS FOR USE

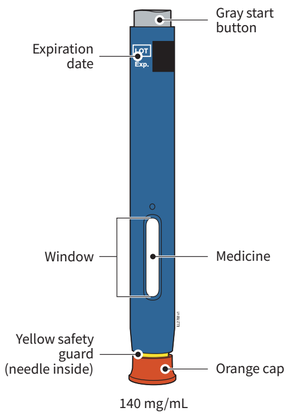
REPATHA® [ri-PAth-a]
(evolocumab)
injection, for subcutaneous use
140 mg/mL
prefilled single-dose SureClick® autoinjector

This Instructions for Use contains information on how to inject REPATHA with a SureClick autoinjector.

If your healthcare provider decides that you or a caregiver may be able to give your injections of REPATHA at home, you should receive training on the right way to prepare and inject REPATHA. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider or nurse.

The medicine in the REPATHA autoinjector is for injection under the skin (subcutaneous injection). See the REPATHA Patient Information for information about REPATHA.

Getting to know the prefilled autoinjector



Important Information You Need to Know Before Injecting REPATHA

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- Check the autoinjector label and prescription to make sure you have the correct medicine and dose.
- **Do not** use the autoinjector if the carton is damaged or the seal is broken.
- **Do not** use the autoinjector after the expiration date on the label.
- **Do not** shake the autoinjector.
- **Do not** remove the orange cap from the autoinjector until you are ready to inject.
- **Do not** use the autoinjector if it has been frozen.
- **Do not** use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector, and call 1-844-REPATHA (1-844-737-2842).
- The autoinjector is not made with natural rubber latex.

Frequently asked questions:

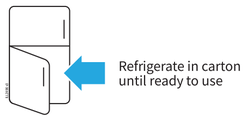
For additional information and answers to frequently asked questions, visit **www.repatha.com**.

Where to get help:

If you want more information or help using REPATHA:

- Contact your healthcare provider,
- Visit **www.repatha.com**, or
- Call 1-844-REPATHA (1-844-737-2842).

Storing and Preparing to Inject REPATHA



1 Refrigerate the autoinjector carton until you are ready to use it.

- Keep the autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the autoinjector in the original carton to protect it from light or physical damage.
- **Do not** freeze the autoinjector.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the autoinjector and all medicines out of the sight and reach of children.

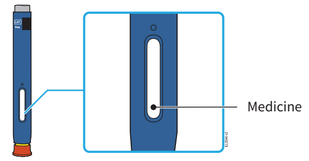
2 Wait 30 minutes for the autoinjector to reach room temperature.

- Remove the number of autoinjectors you need for your injection and put any unused autoinjectors back into the refrigerator.
- Let the autoinjector warm up naturally.
- **Do not** heat the autoinjector with hot water, a microwave, or direct sunlight.
- **Do not** shake the autoinjector at any time.
- Using the autoinjector at room temperature makes sure the full dose is delivered and allows for a more comfortable injection.

3 You may keep REPATHA at room temperature for up to 30 days, if needed.

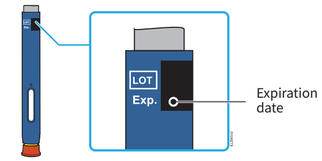
- For example, when you are traveling, you may keep REPATHA at room temperature.
  - Keep it at room temperature between 68°F to 77°F (20°C to 25°C).
  - Record the date you removed it from the refrigerator and use it within **30** days.

Important: Place the autoinjector in a sharps disposal container if it has reached room temperature and has not been used within **30** days.



4 Inspect the medicine. It should be clear and colorless to slightly yellow.

- It is okay to see air bubbles.
- **Do not** use the autoinjector if the medicine is cloudy, discolored, or contains flakes or particles.

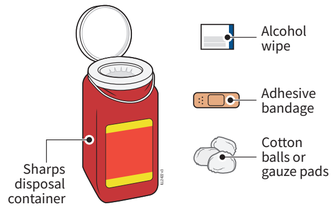


5 Check the expiration date (Exp.) and inspect the autoinjector for damage.

- **Do not** use the autoinjector if the expiration date has passed.
- **Do not** use the autoinjector if:
  - the orange cap is missing or loose in carton,
  - it has cracks or broken parts, or
  - it has been dropped on a hard surface.

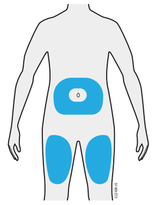
Important: If the medicine is cloudy, discolored, or contains flakes or particles, or if the autoinjector is damaged or expired, call 1-844-REPATHA (1-844-737-2842).

Getting Ready to Inject REPATHA



6 Gather and place the following items for your injection on a clean, flat, and well-lit surface:

- REPATHA autoinjector (room temperature),
- Sharps disposal container [see Completing the Injection and Disposal],
- Alcohol wipe,
- Adhesive bandage, and
- Cotton balls or gauze pads.



7 Select 1 of these injection sites.

- Select the thigh or stomach (except for 2 inches around the belly button).
- Someone else can inject in your thigh, stomach, or back of your upper arm.
- Change injection site each time, shifting the area of the injection to avoid skin irritation.

Important: Avoid areas with scars or stretch marks, or where the skin is tender, bruised, red, hard, raised, thick or scaly skin patch, or lesion.

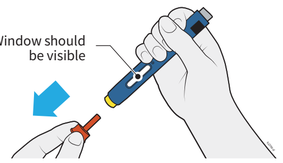
8 Wash your hands thoroughly with soap and water.

9 Clean the injection site with an alcohol wipe.

- Let the skin dry on its own.
- **Do not** touch this area again before injecting.

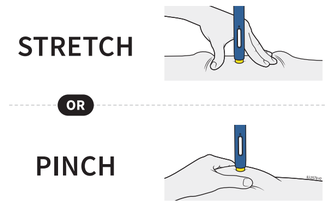
Injecting REPATHA

Important: Only remove the orange cap when you can inject right away (within 5 minutes) because the medicine can dry out. **Do not** recap.



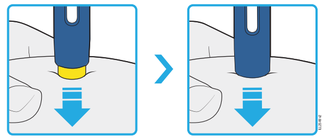
10 Grasp the autoinjector so you can see the window. Pull the orange cap straight off. You may need to pull hard.

- **Do not** twist, bend, or wiggle the orange cap to pull it off.
- **Never** put the orange cap back on. It may damage the needle.
- **Do not** put your finger inside the yellow safety guard.
- It is normal to see a drop of medicine come out of the needle or yellow safety guard.



11 Stretch or pinch the skin to create a firm surface at the injection site until the injection is finished. Place the yellow safety guard straight against the skin.

- Make sure you can see the window.
- Make sure the autoinjector is positioned straight on the injection site (at a 90-degree angle).

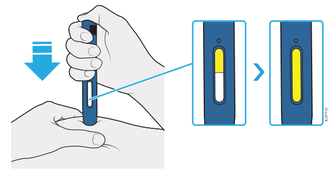


12 Firmly push the autoinjector down until the yellow safety guard stops moving. Hold the autoinjector down, do not lift.

- The yellow safety guard pushes in and unlocks the gray start button.

13 Keep pushing the autoinjector down and press the gray start button to start the injection.

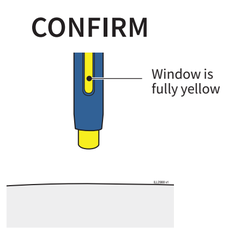
- You may hear or feel a click.
- The window starts to turn yellow.
- It is okay to let go of the gray start button.



14 Keep pushing the autoinjector down. Wait for the window to turn fully yellow.

- The injection may take up to **15** seconds to complete.
- You may hear or feel a click.
- After the window turns fully yellow, lift the autoinjector away from the skin.
- The yellow safety guard locks around the needle.

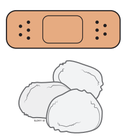
Completing the Injection and Disposal



15 Confirm a full dose of medicine was injected.

- **Do not** touch the yellow safety guard.
- A small drop of liquid on the injection site is okay.

Important: If the window has not turned fully yellow, or if it looks like the medicine is still coming out, a full dose was not injected. Call your healthcare provider right away.



16 Check the injection site.

- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site.
- Apply an adhesive bandage if necessary.

17 Place the used autoinjector and orange cap in an FDA-cleared sharps disposal container.

Important: Do not throw away the autoinjector in your household trash.

- **Do not** reuse the autoinjector.
- **Do not** touch the yellow safety guard.

Additional information about your sharps disposal container

If you do not have an 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.

Disposing of sharps disposal containers:

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.

Keep the autoinjector and sharps disposal container out of the sight and reach of children.

REPATHA (evolocumab)

AMGEN

Manufactured by:
Amgen Inc.
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Thousand Oaks, California 91320-1799
U.S. License Number 1080

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.
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For more information or help call 1-844-REPATHA (1-844-737-2842).