

Instructions For Use for Patients

INSTRUCTIONS FOR USE

Repatha® [ri-PATH-a]
(evolocumab)
injection, for subcutaneous use
140 mg/mL
prefilled single-dose pen



This Instructions for Use contains information on how to inject Repatha with a prefilled pen.

- If your healthcare provider decides that Repatha injections may be given at home, you or your caregiver should receive training on the right way to prepare and inject Repatha. You should not inject until you or your caregiver have been shown the right way to give the injections by your healthcare provider or nurse.
- The medicine in the prefilled pen is for injection under the skin (subcutaneous injection). See the Repatha Patient Information for information about Repatha.

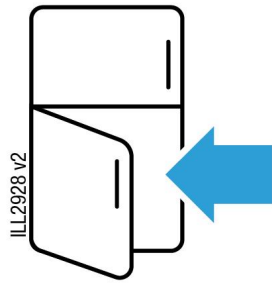
Important Information You Need to Know Before Injecting Repatha

- You should not give the injection until you have fully read and understood this Instructions for Use.
- **Do not** shake the prefilled pen.
- The prefilled pen is not made with natural rubber latex.

Dosing

- The prefilled pen contains a 140 mg dose of Repatha.
 - If your prescribed dose is **140 mg**: Use **one (1) 140 mg** prefilled pen to administer your dose.
 - If your prescribed dose is **420 mg**: Use **three (3) 140 mg** prefilled pens and administer all three injections one at a time **within 30 minutes** to complete your 420 mg dose.
 - Check the prefilled pen label and prescription to make sure you have the correct medicine, dose and number of prefilled pens.
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Storage Information



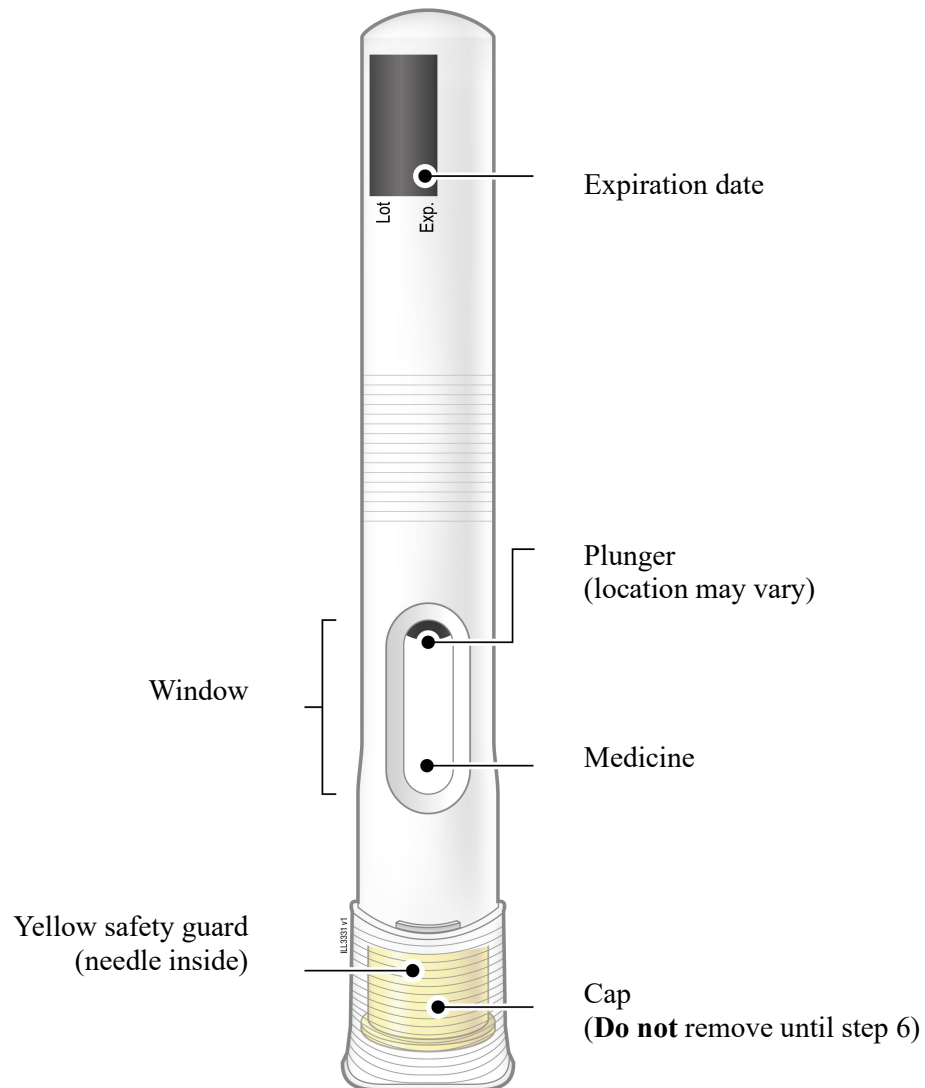
Store refrigerated between
36°F to 46°F (2°C to 8°C)

- Keep the prefilled pen in the original carton to protect it from light and physical damage.
- **Do not** freeze the prefilled pen or store in extreme heat.
- You may keep the prefilled pen at room temperature between 68°F to 77°F (20°C to 25°C) for up to 30 days, if needed.

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

Getting to Know the Prefilled Pen

Side A



Pull to see instructions



Sharps disposal container



Alcohol wipe



Adhesive bandage



Cotton balls or gauze pads

Gather the above items for the injection on a clean, flat, and well-lit surface.

Where to get help

For more information or help using Repatha:

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



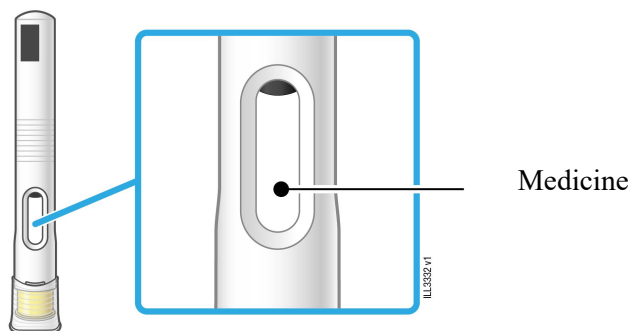
Scan the QR code for optional information.

Getting Ready for the Injection

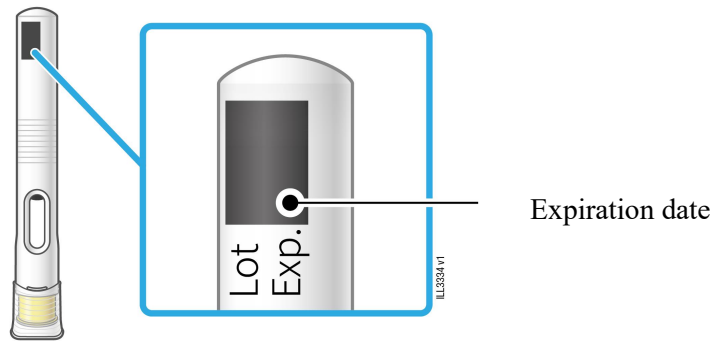


1 Remove the pens from the refrigerator. Wait at least 30 minutes for it to warm naturally to room temperature.

- Only remove the number of prefilled pens needed for a full dose of medicine.
- **Do not** heat the prefilled pen with hot water, a microwave, or direct sunlight.
- Put any unused prefilled pens back into the refrigerator.



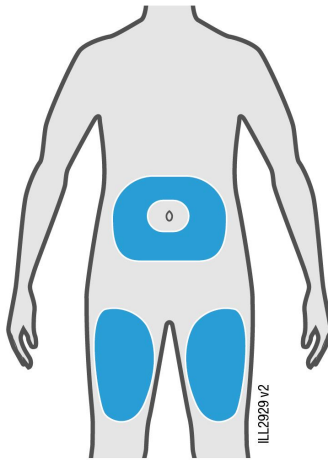
2 Inspect the medicine. It should be clear and colorless to slightly yellow. It is okay to see air bubbles.



3 Check the expiration date (Exp.) and inspect the prefilled pen for damage.

Important: Do not use the prefilled pen and call 1-844-REPATHA (1-844-737-2842) if:

- the medicine is cloudy, discolored, or has particles,
- it has expired,
- the prefilled pen is damaged, has been dropped, the cap is missing or loose in the carton, or
- it has been kept at room temperature for longer than 30 days.



4 Select the thigh or stomach for the injection site.

- Only a caregiver or healthcare provider should inject in the back of the upper arm.
- Choose a different site for each injection.

Important: Avoid areas with scars or stretch marks, or where the skin is tender, bruised, red, or hard. Avoid 2 inches around the belly button.



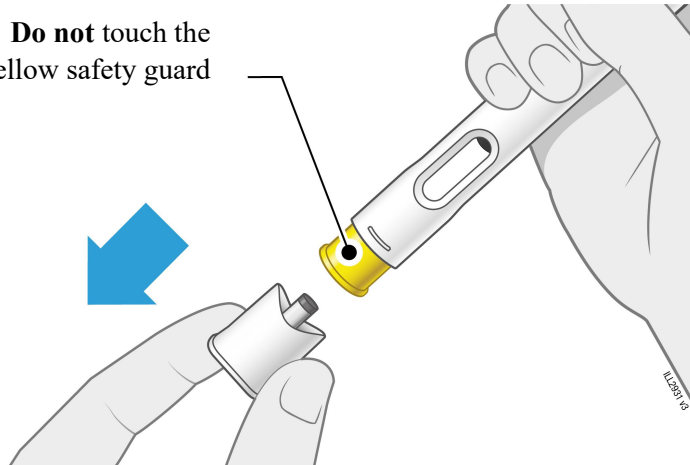
5 Wash your hands with soap and water. Clean the skin at the injection site with an alcohol wipe.

- Let the skin dry naturally.
- **Do not** blow on or touch the injection site again.

Injecting Repatha

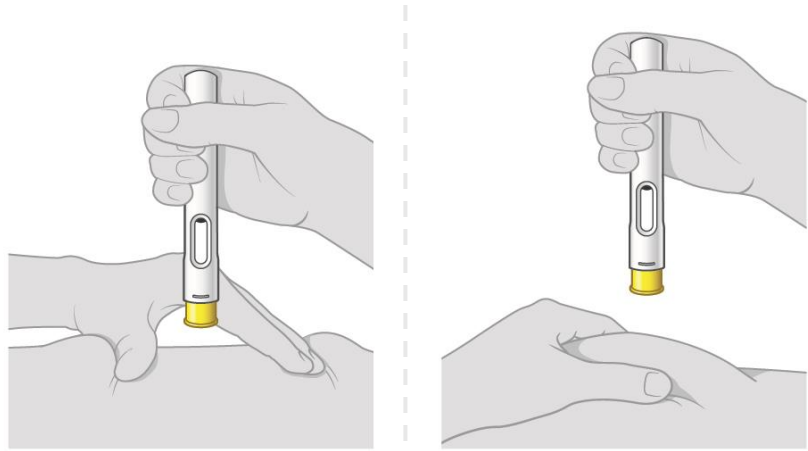
Important: Only remove the cap when you can inject the medicine within 5 minutes. **Do not** recap.

**Do not touch the
yellow safety guard**



6 Pull hard or twist the cap to remove it. Never put the cap back on as it may damage the needle.

- It is okay to see a few drops of medicine come out of the needle.
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Stretch

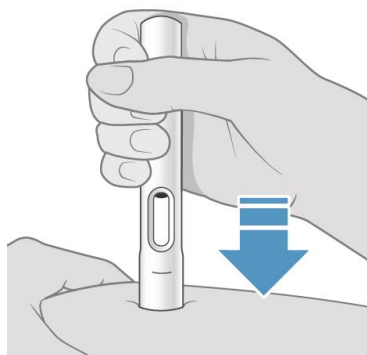
Pinch

- 7** Grasp the prefilled pen so you can see the window. Create a firm surface at the injection site.
- If needed, stretch or pinch the skin to create a firm surface at the injection site until the injection is finished. **Pinching is required for children under 12 years of age.**
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Be patient.

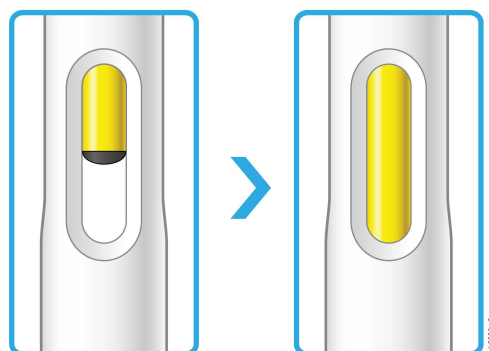
The injection
may take up to
15 seconds.

PUSH and HOLD



- 8** To start the injection, place the pen on your skin. Push down and hold firmly without releasing.
- The yellow safety guard will disappear, and you may hear a click.

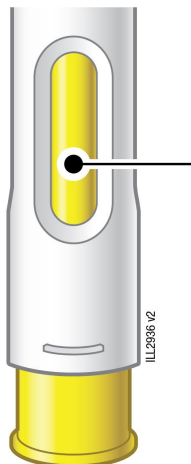
WATCH until COMPLETE



- 9** Continue to hold the prefilled pen down. The injection is complete when the window turns fully yellow. You may hear a second click.

Completing the Injection and Disposal

CONFIRM



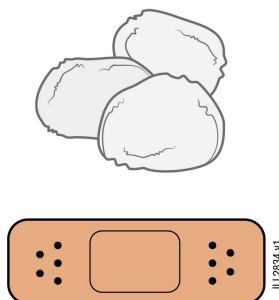
Window is fully yellow

- 10** Confirm all medicine was injected.
- A small drop of liquid on the injection site is okay.
 - Call your healthcare provider if you have not received a full injection of medicine.
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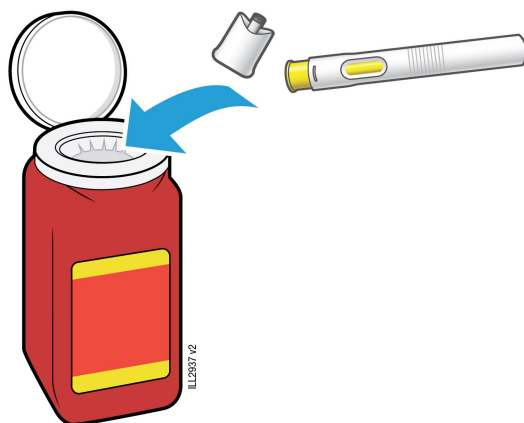
Pull to see instructions





11 Check the injection site.

- **Do not** rub the injection site.
- If there is blood, use a cotton ball and apply an adhesive bandage.



12 Place the used prefilled pen and cap in a sharps disposal container.

- **Do not** throw away the prefilled pen in your household trash.
- **Do not** reuse the prefilled pen.

For more information or help call 1-844-REPATHA (1-844-737-2842).

If prescribed a 420 mg dose: Use 3 prefilled pens. Dispose of each used pen and cap, then inject with a new pen at a different injection site. Give all 3 injections within 30 minutes.

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.

Throwing away (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 prefilled pen and sharps disposal container out of the sight and reach of children.



Manufactured by:

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

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