

Instructions For Use
PRALUENT® (PRAHL-u-ent)
(alirocumab)
Injection, for Subcutaneous Injection
Single-Dose Pre-Filled Pen (75 mg/mL)

Important Information

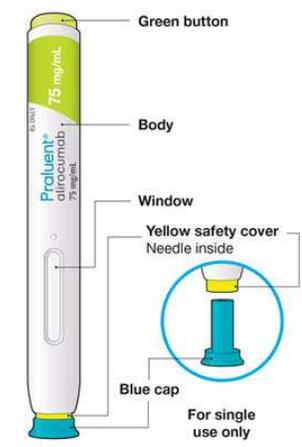
- The device is a single-dose disposable pen. It contains 75 mg of PRALUENT (alirocumab) in 1 mL.
- The PRALUENT pen contains medicine prescribed by your healthcare provider.
- The medicine is injected under your skin and can be given by yourself or someone else (caregiver).
- It is important that you do not try to give yourself or someone else the injection unless you have received training from your healthcare provider.
- In children aged 8 to 11 years, PRALUENT must be given by a caregiver.
- In children aged 12 to 17 years, it is recommended that PRALUENT be given by or under supervision of an adult.
- This pen can only be used for 1 single injection, and must be thrown away (discarded) after use.
- Read all of the instructions carefully before using the PRALUENT pen.
- Follow these instructions every time you use a PRALUENT pen.
- **Do not** touch the yellow safety cover.
- **Do not** use the pen if it has been dropped or damaged.
- **Do not** use the pen if the blue cap is missing or not securely attached.
- **Do not** re-use a pen.

Storage of PRALUENT

- Store unused pens in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- **Do not** freeze.
- **Do not** expose the pen to extreme heat or direct sunlight.
- **Do not** shake.
- PRALUENT should be allowed to warm to room temperature for 30 to 40 minutes before use.
- If needed, PRALUENT may be kept at room temperature up to 77°F (25°C) for 30 days in the original carton to protect from light. **Do not** store above 77°F (25°C).
- After PRALUENT is removed from the refrigerator it must be used within 30 days or thrown away.
- Keep the PRALUENT pens and all medicines out of the reach of children.

Keep this leaflet. If you have questions, ask your healthcare provider or call 1-844-PRALUENT (1-844-772-5836).

The parts of the PRALUENT pen are shown in this picture.



Step A: Getting ready for your injection.

Before you start you will need:

- the PRALUENT pen
- 1 alcohol wipe
- 1 cotton ball or gauze
- a sharps container or a puncture-resistant container (see Step B8)

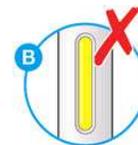
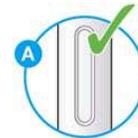
A1: Look at the label on the pen.

- Check that you have the correct product and the correct dose.
- Check the expiration date (EXP): **do not** use if this date has passed.



A2: Look at the window.

- Check the liquid is clear, colorless to pale yellow and free from particles (see Figure A).
- You may see air bubbles. This is normal.
- **Do not** use if the window appears solid yellow (see Figure B).
- **Do not** use this medicine if the solution is discolored or cloudy, or if it contains visible flakes or particles.



A3: Let the pen warm up at room temperature for 30 to 40 minutes.

- This is important for administering the entire dose and helps minimize discomfort.
- Take PRALUENT out of the refrigerator to warm up before using.
- **Do not** heat the pen, let it warm up on its own.
- **Do not** put the pen back in the refrigerator.

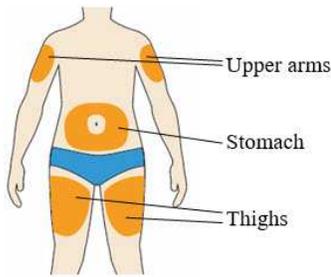


A4: Prepare the injection site.

- Wash your hands with soap and water and dry with a towel.
- Clean skin in the injection area with an alcohol wipe.
- You can inject into your (see picture):
 - thighs
 - stomach (except for the 2 inch area around your belly button)
 - upper arms
- You can stand or sit to give yourself an injection.

Important:

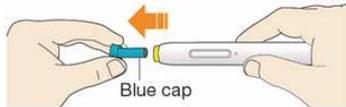
- Change (rotate) your injection site each time you give yourself an injection. If you need to use the same injection site, make sure it is not the same spot on the site you used last time.
- **Do not** inject into areas where the skin is tender, bruised, hard, or red. **Do not** inject PRALUENT into areas with visible veins, scars or stretch marks.



Step B: How to give your injection.

B1: After completing all steps in "Step A: Getting ready for your injection", pull off the blue cap.

- Do not pull off the cap until you are ready to inject.
- Do not put the blue cap back on.



B2: Hold the PRALUENT pen like this.

- Do not touch the yellow safety cover.
- Make sure you can see the window.



B3: Press the yellow safety cover on your skin at roughly a 90° angle.

- For children younger than 12 years of age, pinching the skin before and during the injection is required.
- In adults and children aged 12 years and older, pinching of skin may be required to make the injection site firm.
- Press and firmly hold the pen against your body until the yellow safety cover is no longer visible. The pen will not work if the yellow safety cover is not depressed fully.



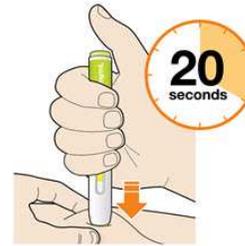
B4: Push and immediately release the green button with your thumb.

- You will hear a click. Your injection has now started.
- The window will start to turn yellow.



B5: Keep holding the pen against your skin after releasing the button.

- The injection may take up to 20 seconds.



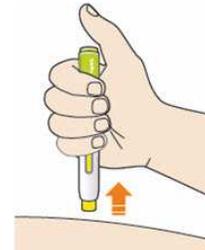
B6: Check the window has turned yellow, before removing the pen.

- Do not remove the pen until the entire window has turned yellow.
- Your injection is complete when the window has turned completely yellow, you may hear a second click.
- If the window does not turn completely yellow, call 1-844-772-5836 for help. Do not give yourself a second dose without speaking to your healthcare provider.



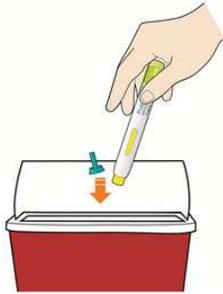
B7: Pull pen away from your skin.

- Do not rub the skin after the injection.
- If you see any blood, press a cotton ball or gauze on the site until the bleeding stops.



B8: Throw away (Discard) pen and cap.

- **Do not** put the blue cap back on.
- Throw away pen and cap in a puncture-resistant container immediately after they have been used.

**Disposing of used pens:**

- Put your used pens in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) pens and caps 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.

Keep PRALUENT and all medicines out of the reach of children.

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

REGENERON

Manufactured by:

Regeneron Pharmaceuticals, Inc.

Tarrytown, NY 10591

U.S. License # 1760

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Revised: March 2024

US.PRA.24.03.0003