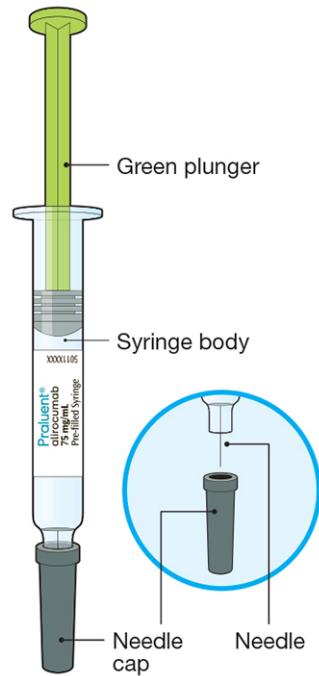


Instructions For Use
PRALUENT[®] (PRAHL-u-ent)
(alirocumab)
Injection, for Subcutaneous Injection
Single-Dose Pre-Filled Syringe (75 mg/mL)

Important Information	
<ul style="list-style-type: none">• The device is a single-dose pre-filled syringe. It contains 75 mg of PRALUENT (alirocumab) in 1 mL.• The PRALUENT syringe 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.• This syringe can only be used for 1 single injection, and must be discarded after use.	<ul style="list-style-type: none">• Read all of the instructions carefully before using the PRALUENT syringe.• Follow these instructions every time you use a PRALUENT syringe.• Do not touch the needle.• Do not use the syringe if it has been dropped or damaged.• Do not use the syringe if the gray needle cap is missing or not securely attached.• Do not re-use a syringe.
Storage of PRALUENT <ul style="list-style-type: none">• Store unused syringes in the refrigerator at 36°F to 46°F (2°C to 8°C) in the outer carton to protect from light.• Do not freeze.• Do not expose the syringe 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. Do not keep PRALUENT at room temperature for more than 24 hours.• Keep the PRALUENT syringes 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 syringe are shown in this picture.



Step A: Getting ready for your injection

Before you start you will need:

- the PRALUENT syringe
- 1 alcohol wipe
- 1 cotton ball or gauze
- a puncture-resistant container (see Step B6)

A1: Before you start.

- Take the syringe out of the packaging by holding the syringe body.
- Check the expiration date: **do not** use if this date has passed.



A2: Look at the label on the syringe.

- Check that you have the correct product and the correct dose (green plunger for 75 mg/mL).
- Check the liquid is clear, colorless to pale yellow and free from particles .
- Check that the syringe is not open or damaged.
- **Do not** use this medicine if the solution is discolored or cloudy, or if it contains visible flakes or particles.

A3: Let the syringe 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 syringe, let it warm up on its own.
- Use the syringe as soon as possible after it has warmed up.
- **Do not** put the syringe back in the refrigerator.

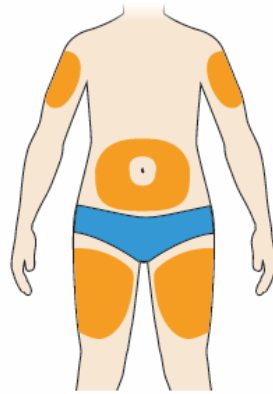


A4: Prepare the injection site.

- 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 below picture):
 - thighs
 - stomach (except for the 2 inch area around your navel)
 - upper arms
- You can stand or sit to give yourself an injection.

Important:

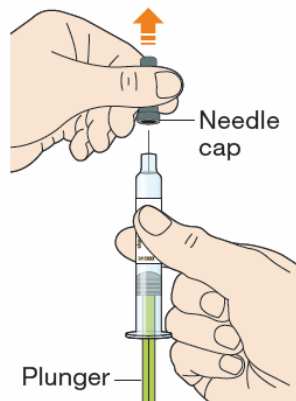
- Change (rotate) your injection site each time you give yourself an injection. If you need to use the same injection site, make sure it is not the same spot on the site you used last time.
- **Do not** inject into areas where the skin is injured, tender, hard, red, or hot. **Do not** inject PRALUENT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



Step B: How to give your injection

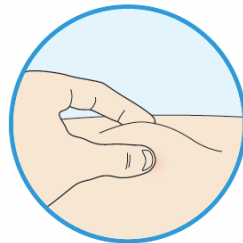
B1: After completing all steps in “Step A: Getting ready for your injection”, pull off the needle cap.

- **Do not** pull off the cap until you are ready to inject.
- Hold the syringe in the middle of the syringe body with the needle pointing away from you.
- Keep your hand away from the plunger.
- **Do not** try to remove any air bubbles in the syringe before the injection.
- **Do not** put the gray cap back on the needle.



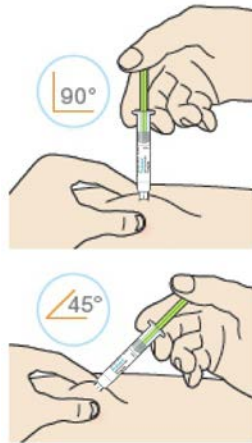
B2: If needed pinch the skin.

- Use your thumb and first finger to pinch a fold of skin at the injection site.
- Hold the skin like this during the entire injection.



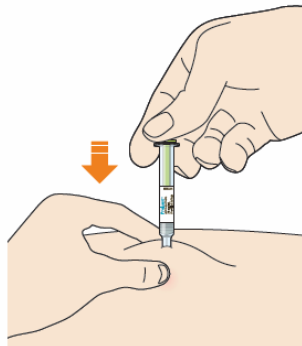
B3: Insert the needle into the fold of skin with a quick dart-like motion.

- Inject the medicine at a 90° angle if you can pinch 2 inches of skin.
- Inject the medicine at a 45° angle if you can only pinch 1 inch of skin.



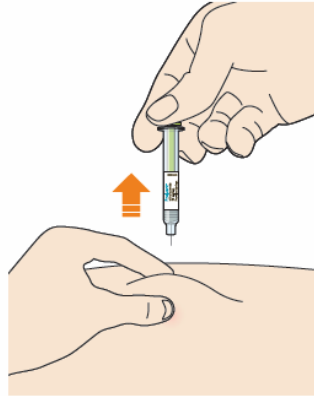
B4: Push the plunger down.

- Inject all of the medicine by slowly and steadily pushing down the plunger.
- You may have to push harder on the plunger than for other injectable medicines.



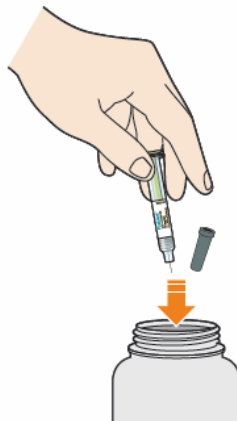
B5: Before you remove the needle check the syringe is empty.

- The time required for injection to give the entire dose may be longer than for other injectable medicines.
- **Do not** remove the syringe until it is completely empty.
- Pull the needle out of the skin at the same angle as it was inserted.
- **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.



B6: Discard syringe and cap.

- **Do not** put the gray needle cap back on.
- **Do not** re-use the syringe.
- Throw away syringe and cap in a puncture-resistant container immediately after they have been used.



Disposing of used prefilled syringes and needles:

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

SANOFI 

Manufactured by:
sanofi-aventis U.S. LLC
Bridgewater, NJ 08807
A SANOFI COMPANY
U.S. License # 1752

Marketed by: sanofi-aventis U.S. LLC (Bridgewater, NJ 08807)
and Regeneron Pharmaceuticals, Inc. (Tarrytown, NY 10591)

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