

PRALUENT PRE-FILLED PEN

QUICK REFERENCE GUIDE


Praluent[®]
(alirocumab) Injection 75mg/mL
150mg/mL



STEP-BY-STEP INSTRUCTIONS on how to use PRALUENT

Please see full Important Safety Information on pages 26 and 27.
Please see full [Prescribing Information](#) available at
www.PRALUENT.com.

WHAT IS PRALUENT® (alirocumab)?

PRALUENT is an injectable prescription medicine used:

- in adults with cardiovascular disease to reduce the risk of heart attack, stroke, and certain types of chest pain conditions (unstable angina) requiring hospitalization.
- 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 [HeFH]), to reduce low-density lipoprotein cholesterol (LDL-C) or bad cholesterol.
- along with other LDL-lowering treatments in adults with a type of high cholesterol called homozygous familial hypercholesterolemia, who need additional lowering of LDL-C.
- along with diet and other LDL-C lowering treatments in children aged 8 years and older with HeFH to reduce LDL-C.

It is not known if PRALUENT is safe and effective in children who are younger than 8 years of age or in children with other types of high cholesterol (hyperlipidemias).

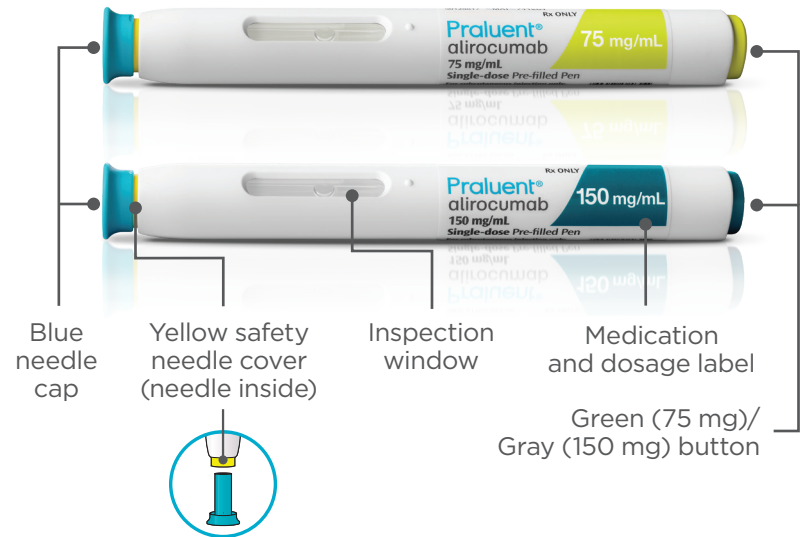
IMPORTANT SAFETY INFORMATION

Do not use PRALUENT if you are allergic to alicrocumab or to any of the ingredients in PRALUENT.

Please see full Important Safety Information on pages 26 and 27. Please see full [Prescribing Information](#) available at www.PRALUENT.com.

PRALUENT COMES IN AN EASY-TO-USE PRE-FILLED PEN

- Injected under the skin* **every 2 weeks** (75 mg or 150 mg doses) or **every 4 weeks** (300 mg monthly dose)[†]



*Subcutaneously.

[†]Use PRALUENT as prescribed by your healthcare provider. If your healthcare provider prescribes you the monthly dose, you will give yourself 2 separate 150 mg injections in a row, using a different pen for each injection, at two different injection sites.

Praluent®
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150mg/mL

IMPORTANT INFORMATION

- The device is an easy-to-use, single 1 mL pre-filled pen. It contains 75 mg or 150 mg of PRALUENT® (alirocumab)
- If your healthcare provider prescribes you the monthly dose, you will give yourself 2 separate 150 mg injections in a row, using a different pen for each injection, at two different injection sites
- The pen is not made with natural rubber latex
- The medicine is injected under your skin and can be given by yourself or someone else (caregiver)
- 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 after use. For the monthly 300 mg dose, throw out the first 150 mg pen before repeating the steps to administer your second injection
- If needed, PRALUENT may be kept at room temperature up to 77°F in the original carton and must be used within 30 days or discarded

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DO

- ✓ Keep the PRALUENT Pen out of the sight and reach of children
- ✓ Read the Patient Information and Instructions For Use carefully before using the PRALUENT Pen
- ✓ Follow these instructions every time you use a PRALUENT Pen
- ✓ Store unused pens in the refrigerator at 36°F to 46°F in the original carton to protect from light

DO NOT

- ✗ Do not try to give yourself or someone else the injection unless you have received training from your healthcare provider
- ✗ Do not store at temperatures above 77°F
- ✗ Do not leave out of the refrigerator for more than 30 days

IMPORTANT SAFETY INFORMATION

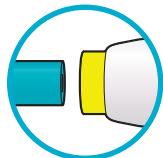
Before you start using PRALUENT, tell your healthcare provider about all of your medical conditions, including allergies, and if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed.


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PRALUENT® (alirocumab) PEN KEY FEATURES



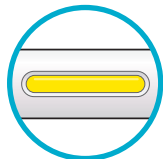
The ready-to-use PRALUENT Pen was designed for self-injection at home



The yellow safety needle cover keeps the needle hidden throughout the entire injection



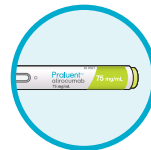
A “click” sound tells you that the injection has started



The window turns yellow when the injection is completed so you know the full dose has been delivered

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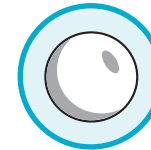
Before you start your injection, you will need:



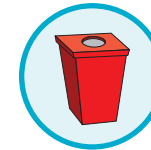
The PRALUENT Pen



1 alcohol wipe



1 cotton ball or gauze pad



A sharps disposal container or a puncture-resistant container (see step 8 on page 19)

For self-injecting the monthly 300 mg dose, prepare two 150 mg pens.

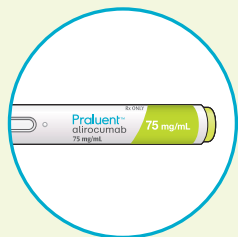
IMPORTANT SAFETY INFORMATION

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

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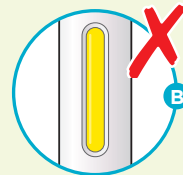
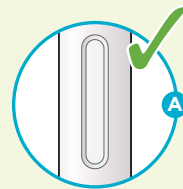
GETTING READY FOR AN INJECTION

1. LOOK at the label



- Check that you have the correct product and the correct dose
- Check the use-by date on the label; do not use if this date has passed
- **DO NOT** use the pen if it has been dropped or damaged

2. LOOK at the window

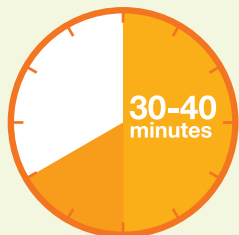


- Check that liquid is clear, colorless to pale yellow, and free from particles (see picture **A**). If not, do not use
- You may see air bubbles. This is normal
- **DO NOT** use if the window appears solid yellow (see picture **B**)

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GETTING READY FOR AN INJECTION (cont'd)

3. BRING to room temperature for 30-40 minutes



- Let two 150 mg pens come to room temperature for the monthly 300 mg dose
- **DO NOT** heat the pen; let it warm up on its own
- **DO NOT** expose the pen to direct sunlight
- You may want to set a timer for 30-40 minutes to remind you when PRALUENT has reached room temperature and is ready to be injected
- **DO NOT** put the pen back in the refrigerator

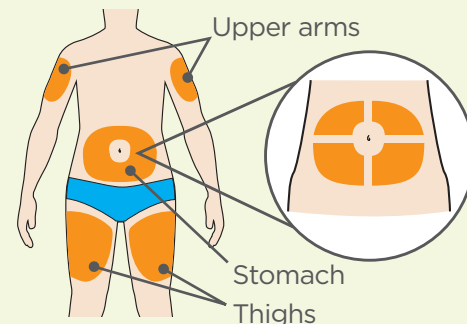
If needed, PRALUENT may be kept at room temperature up to 77°F in the original carton and must be used within 30 days or discarded

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4. PREPARE the injection site

INJECTION SITES

- Top of thigh
- Stomach (except for the 2 inch area around your belly button)
- Outer side of your upper arms (for caregivers)

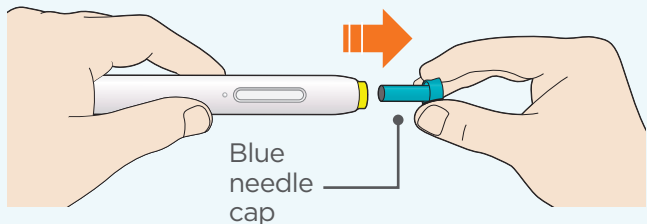


- Wash your hands with soap and water and dry with a towel
- Clean skin in the injection area with an alcohol wipe
- **DO NOT** inject into areas where the skin is tender, bruised, hard, or red
- **DO NOT** inject PRALUENT into areas with visible veins, scars or stretch marks
- Change your injection 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 you used last time
- Use a different injection site for the second injection for the monthly 300 mg dose

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HOW TO INJECT

1. PULL off the blue needle cap



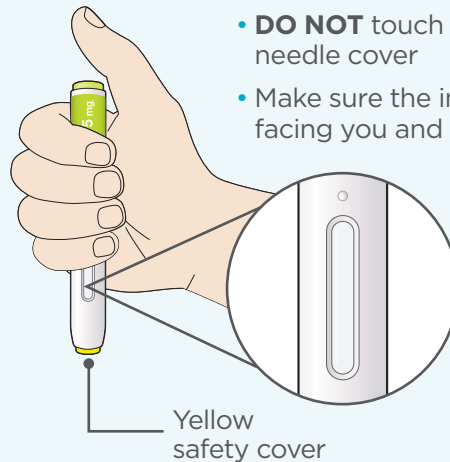
DO NOT touch the yellow safety needle cover

- **DO NOT** pull off the cap until you are ready to inject
- **DO NOT** use the pen if the blue needle cap is missing or not securely attached
- **DO NOT** put the cap back on

2. HOLD the pen like this so you can see the window

Your thumb should not touch the green button yet

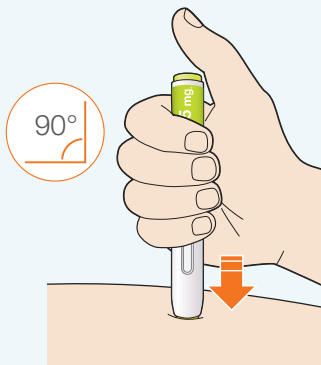
- **DO NOT** shake the pen
- **DO NOT** touch the yellow safety needle cover
- Make sure the inspection window is facing you and that you can see it



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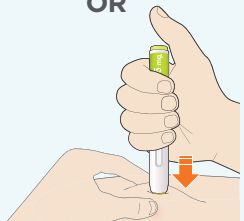
HOW TO INJECT (cont'd)

3. PRESS down the yellow safety needle cover on your skin

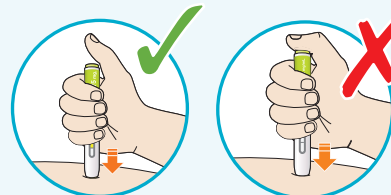


- Press the yellow safety needle cover straight down on your skin at roughly a 90° angle
- **DO NOT** lift the pen from your skin
- Use the same pressure for the entire injection

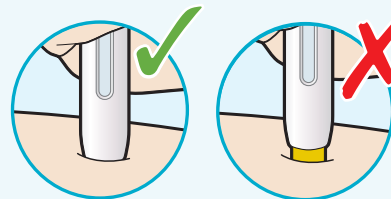
OR



- 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



- **DO NOT** touch the green button yet



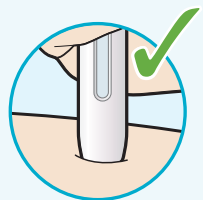
- Firmly press down until the yellow safety needle cover disappears into the pen and is no longer visible

The pen will not work if the yellow safety needle cover is not pushed all the way down

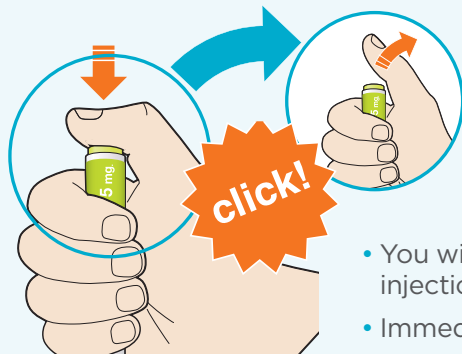
Please see full Important Safety Information on pages 26 and 27.
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HOW TO INJECT (cont'd)

4. PUSH and immediately release the button

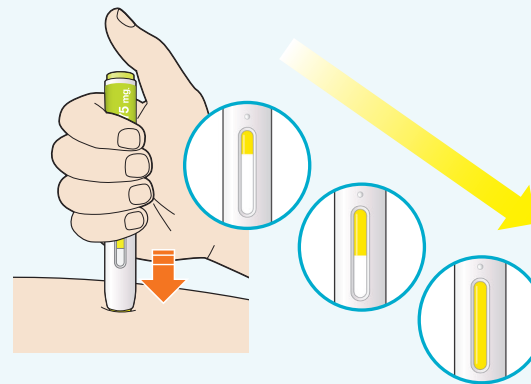


- Continue to firmly press down so that the yellow safety needle cover is not visible



- You will hear a “click.” Your injection has now started
- Immediately release the button
- The window will start to turn yellow

5. HOLD in place until entire window is yellow

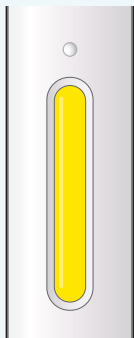


- Use the same pressure for the entire injection
- The injection may take up to 20 seconds

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HOW TO INJECT (cont'd)

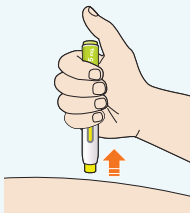
6. CHECK that the window has turned yellow



- **DO NOT** remove the pen until the entire window has turned yellow
- You may hear a second “click” when the injection is complete
- If the window does not turn completely yellow, do not give yourself a second dose without speaking to your doctor, pharmacist, or nurse

Injection is complete when window turns completely yellow

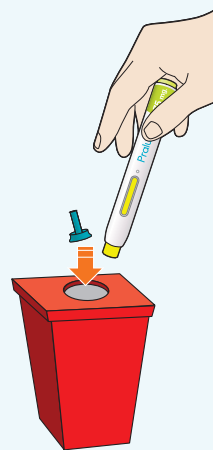
7. LIFT pen away from your skin



- **DO NOT** rub the skin after the injection
- You may see a drop of blood at the injection site

Please see full Important Safety Information on pages 26 and 27.
Please see full Prescribing Information available at
www.PRALUENT.com.

8. THROW away pen and needle cap



- **DO NOT** put the blue cap back on
- Throw away pen and needle cap into a puncture-resistant container right after use
- For the monthly 300 mg dose, throw out the first 150 mg pen before repeating the steps for your second injection
- Always keep the container out of the sight and reach of children
- **DO NOT** reuse the pen

When self-injecting the monthly 300 mg dose, repeat ALL steps with a second 150 mg pen at a different injection site

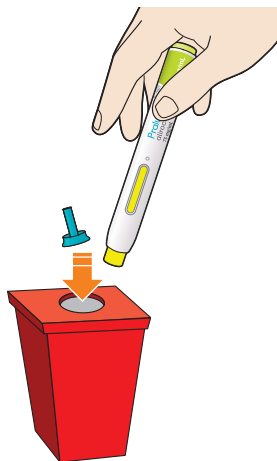
HOW TO THROW OUT YOUR PEN

- Put your used pens in an FDA-cleared sharps disposal container right away after use. **DO NOT throw out pens and caps in your household trash**

- For the monthly 300 mg dose, throw out the first 150 mg pen before repeating the steps for your second injection

- 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



- 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 where you live, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>

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

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www.PRALUENT.com.

FREQUENTLY ASKED QUESTIONS

1. How should I store PRALUENT® (alirocumab)?

- PRALUENT should be stored in the refrigerator at 36°F-46°F in the original carton protected from light. **DO NOT** freeze the pen. **DO NOT** expose to extreme heat. **DO NOT** shake
- You should remove the PRALUENT Pen from the refrigerator 30 to 40 minutes prior to use and allow it to come to room temperature on its own. This will make the injection less uncomfortable
- If you have been prescribed the monthly 300 mg dose, you will need to let two 150 mg pens come to room temperature
- If needed, PRALUENT may be kept at room temperature (up to 77°F) in the original carton for up to 30 days. **DO NOT** store at temperatures above 77°F
- After removal from the refrigerator, PRALUENT must be used within 30 days or discarded

2. Is it okay to use the pen if I see air bubbles in the window?

- Yes, it is normal to see air bubbles in the window. This is okay

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3. What should I do if I can't push the yellow safety needle cover all the way into the pen while pressing on my skin?

- It may help to pinch the skin to make sure the injection site is firm. You may also consider injecting into an area on your thighs
- Be sure that you keep your thumb off of the green/gray button while pushing the yellow safety needle cover on your skin

IMPORTANT SAFETY INFORMATION

PRALUENT can cause serious side effects, including allergic reactions that can be severe and require treatment in a hospital. Stop using PRALUENT and call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction including a severe rash, redness, hives, severe itching, trouble breathing, or swelling of the face, lips, throat, or tongue.

FREQUENTLY ASKED QUESTIONS (cont'd)

4. What should I do if I can't push the green/gray button?

- First, release the button and check that you have taken off the blue needle cap
- Place the pen on your skin, and press down firmly until the yellow safety needle cover is pushed all the way into the pen. You won't be able to push the button if the yellow safety needle cover is still showing. You might need to pinch the skin with your other hand so it's firm
- Now, push the green/gray button again. You should hear a click. Then release the button

5. What do I do if I forget a dose?

If you inject every 2 weeks:

- Inject your missed dose as soon as you remember, within 7 days of your missed dose
- Then, take your next dose 2 weeks from the day you missed your dose. This will put you back on your original schedule
- If you missed a dose by more than 7 days, wait until your next scheduled dose to restart PRALUENT. This will keep you on your original schedule

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If you inject every 4 weeks:

- Inject your missed dose as soon as you remember within 7 days of your missed dose
- Then, take your next dose 4 weeks from the day you missed your dose. This will put you back on your original schedule
- If you missed a dose by more than 7 days, start a new schedule from the time you remember to take your dose

6. Are there resources to help with injection training?

- Visit PRALUENT.com to watch a self-injection training video

IMPORTANT SAFETY INFORMATION

The common side effects of PRALUENT include: redness, itching, swelling, or pain/tenderness at the injection site; flu or flu-like symptoms; diarrhea; muscle pain; muscle spasms; and bruising. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.


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Before you start using PRALUENT, tell your healthcare provider about all of your medical conditions, including allergies, and if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed.

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

PRALUENT can cause serious side effects, including allergic reactions that can be severe and require treatment in a hospital. Stop using PRALUENT and call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction including a severe rash, redness, hives, severe itching, trouble breathing, or swelling of the face, lips, throat, or tongue.

The common side effects of PRALUENT include: redness, itching, swelling, or pain/tenderness at the injection site; flu or flu-like symptoms; diarrhea; muscle pain; muscle spasms; and bruising. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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Talk to your doctor about the right way to prepare and give yourself a PRALUENT injection and follow the “Instructions For Use” that comes with PRALUENT. In children aged 12 to 17 years, it is recommended that PRALUENT be given by or under the supervision of an adult. In children aged 8 to 11 years, PRALUENT should be given by a caregiver.

For any questions or concerns, or to report side effects with a Regeneron product while enrolled in MyPRALUENT, please contact MyPRALUENT at 1-844-772-5836.



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ELIGIBLE COMMERCIALLY INSURED PATIENTS MAY PAY AS LITTLE AS A \$50 COPAY FOR PRALUENT EACH MONTH*



If eligible, you can use the MyPRALUENT® Copay Card to pay your out-of-pocket costs for your PRALUENT treatment, including deductibles, copays, and coinsurance (up to a maximum annual assistance of \$3,500). Terms and conditions apply.*

To see if you qualify for the MyPRALUENT® Copay Card, call 1-844-PRALUENT (1-844-772-5836).

*Eligible patients with commercial insurance not funded through a government healthcare program subject to an annual cap and other program terms and restrictions. This offer is not valid for prescriptions covered by or submitted for reimbursement under Medicaid, Medicare, VA, DOD, TRICARE, or similar federal or state programs.

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REGENERON®

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