Frequently Asked Questions

Understanding Cholesterol

Do high levels of bad cholesterol matter as much as other risk factors such as diabetes and high blood pressure?

Smoking, cholesterol, blood pressure, and diabetes are ALL major controllable risk factors for heart disease, heart attack, and stroke. The more risk factors you have, the greater your risk.

Should I be concerned with high levels of bad cholesterol even if I feel okay?

High levels of bad cholesterol can lead to the buildup of plaque in the arteries, the most common cause of heart disease, heart attack, and stroke. Plaque buildup most often starts early in life and progresses slowly, often with no symptoms. Even if you feel fine, keeping your bad cholesterol levels in check can reduce your risk of plaque buildup.

Can making healthy changes, such as eating better and exercising more, help manage cholesterol levels?

Healthy lifestyle choices are an important first step toward lowering your risk of heart disease, heart attack, and stroke. However, for some people, lifestyle changes may not be enough. If your bad cholesterol numbers are still not where they should be, talk to your doctor about your options.

What is FH, and what is the difference between HeFH and HoFH?

FH, or familial hypercholesterolemia, is a rare inherited condition caused by mutations in at least one of four known genes that control how the body processes cholesterol, which can lead to very high levels of bad cholesterol. This condition can lead to premature (early) heart disease.

FH can come in two forms, heterozygous familial hypercholesterolemia (HeFH), the common form, which develops when one mutated gene is inherited from one parent, and homozygous familial hypercholesterolemia (HoFH), which develops when a mutated gene is inherited from both parents.

Frequently Asked Questions

About PRALUENT® (alirocumab)

What is PRALUENT?

PRALUENT is a prescription medication used in adults with cardiovascular disease.

PRALUENT can be used to reduce the risk of major adverse cardiovascular (CV) events, such as death from coronary heart disease, heart attack, stroke, or certain types of chest pain conditions (unstable angina) requiring hospitalization, in adults at increased risk for these events.

PRALUENT can also be used along with diet and exercise, to reduce low-density lipoprotein cholesterol (LDL-C) or bad cholesterol in:

- adults with high blood cholesterol levels called hypercholesterolemia.
- adults and children aged 8 years and older with a type of high cholesterol called heterozygous familial hypercholesterolemia (HeFH).
- adults with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH).

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 (hypercholesterolemia).

In a large clinical study of ~19,000 adult patients, PRALUENT was proven to reduce the risk of major adverse cardiovascular (CV) events, such as death from coronary heart disease, heart attack, stroke, or certain types of chest pain conditions (unstable angina) requiring hospitalization, in adults at increased risk for these events.

PRALUENT has also been shown to effectively reduce bad cholesterol.

In other clinical studies (12-24 weeks) of adult patients with heart problems due to plaque in the arteries or with HeFH whose bad cholesterol was not at goal, adding PRALUENT significantly reduced bad cholesterol levels by an average of

43% to 58% from baseline when taken alone or with other cholesterol-lowering medications and a healthy diet.

In a separate clinical study of **pediatric patients aged 8-17 years with HeFH,** adding PRALUENT reduced bad cholesterol levels from baseline by an average of

~31% compared to placebo when taken with cholesterol-lowering medications and a healthy diet at 24 weeks.

In another clinical study of adults with **homozygous familial hypercholesterolemia (HoFH),** PRALUENT lowered bad cholesterol by an average of

36% compared to placebo when used with other cholesterol-lowering medications at 12 weeks.

Is PRALUENT different from a statin?

PRALUENT is not a statin. Statins help lower the production of bad cholesterol. PRALUENT works by blocking a protein (called PCSK9) that may contribute to high levels of bad cholesterol. Adding PRALUENT helps increase your liver's ability to clear bad cholesterol from your bloodstream.

Though they work differently, PRALUENT and statins can work together to lower your bad cholesterol when added to a healthy diet. PRALUENT can be taken with or without a statin.

What is PRALUENT® (alirocumab)?

PRALUENT is an injectable prescription medicine used:

- to reduce the risk of major adverse cardiovascular (CV) events, such as death from coronary heart disease, heart attack, stroke, or certain types of chest pain conditions (unstable angina) requiring hospitalization, in adults at increased risk for these events.
- along with diet and exercise, to reduce low-density lipoprotein cholesterol (LDL-C) or bad cholesterol in:
  - adults with high blood cholesterol levels called hypercholesterolemia.
  - adults and children aged 8 years and older with a type of high cholesterol called heterozygous familial hypercholesterolemia (HeFH).
  - adults with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH).

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 (hypercholesterolemia).

Important Safety Information

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

Please see Important Safety Information throughout document.

Please see full Prescribing Information available at PRALUENT.com.

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

Frequently Asked Questions

PRALUENT® (alirocumab) Safety Information

What are the possible side effects of PRALUENT?

PRALUENT can cause serious side effects, including allergic reactions. PRALUENT may cause 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 most common side effects include:



Redness, itching, swelling, pain, or tenderness at the injection site



Flu



Muscle pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of PRALUENT. Ask your healthcare provider or pharmacist for more information. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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 (hypercholesterolemia).

Can I take PRALUENT with other medications?

PRALUENT can be used along with other lipid-lowering therapies (including statins) if needed, in order to manage your high cholesterol. Tell your healthcare provider or pharmacist about any medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Can I take PRALUENT if I am pregnant or breastfeeding?

Before you start using PRALUENT, tell your healthcare provider if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed.

It is not known if PRALUENT will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking PRALUENT.

You and your healthcare provider should decide if you will take PRALUENT or breastfeed. Do not do both without talking to your healthcare provider first.

If you are pregnant during PRALUENT treatment, you are encouraged to call Regeneron at 1-844-734-6643 to share information about the health of you and your baby.

Please see Important Safety Information throughout document.

Please see full Prescribing Information available at PRALUENT.com.

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

Frequently Asked Questions

Paying for PRALUENT® (alirocumab)

How much does PRALUENT cost?

The cost of PRALUENT will depend on the type of insurance you have.*

The MyPRALUENT® Patient Support Program can help determine what financial support may be available for you. Call **1-844-PRALUENT (1-844-772-5836)** to learn more. We are available Monday to Friday, 8:00 am to 8:00 pm EST.

Please see the questions below for more savings options.

*Because formularies do change and many health plans offer more than one formulary, please check directly with the health plan to confirm coverage.

Are there any savings options available?

There may be an option to help you with the cost of PRALUENT.



If you have private (commercial) insurance:

- You may qualify for the MyPRALUENT® Copay Card and pay as little as $50 per month for your PRALUENT treatment, subject to an annual cap of $3,500. Terms and conditions apply†
- If eligible, you can use this card for PRALUENT copay, coinsurance, and deductibles
- See if you qualify for the MyPRALUENT® Copay Card. Click here to apply or 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.

MyPraluent®

Uninsured and insured patients with no pharmacy coverage (limited to current enrollees)

Eligible patients without insurance and those with insurance lacking pharmacy coverage can re-enroll to receive PRALUENT at no cost for up to 12 months through the MyPRALUENT Patient Assistance Program. Unfortunately, Medicare Part D patients and new enrollees are no longer accepted. Learn more at PRALUENT.com.

If you have limited income and resources and have Medicare:

If you're faced with limited income and resources, there's a US government–funded program that may help you pay some of your Medicare prescription drug costs for all of your prescription medicines. It's called the Extra Help Program (also referred to as Low-Income Subsidy), and it offers eligible patients the following:

- Reduced Medicare Part D premiums
- Lower drug copays

Please see Important Safety Information throughout document.

Please see full Prescribing Information available at PRALUENT.com.

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

Frequently Asked Questions

Getting PRALUENT® (alirocumab)

Where do I get PRALUENT?

You may be able to pick up your PRALUENT prescription from your local retail pharmacy or a specialty pharmacy can deliver it to you.

Note: Once you receive PRALUENT, be sure to put it in the refrigerator. After PRALUENT is removed from the refrigerator, it must be used within 30 days or thrown away.

What happens if I'm not home when my prescription of PRALUENT is delivered?

PRALUENT is shipped in a temperature-controlled container to keep it at the correct temperature during transport and delivery to your home. You do not need to sign for your delivery. However, we encourage you to be home if you can so that you can put PRALUENT into your refrigerator as soon as it arrives.

After removal from the refrigerator, if needed, patients may keep PRALUENT at room temperature up to 77°F (25°C) for a maximum of 30 days in its original carton to protect it from light. If you will not be home the day it is scheduled to be delivered, call your pharmacy. The pharmacy can reschedule the delivery for a day that works for you.

How long can PRALUENT be left out without refrigeration?

If needed, PRALUENT may be left out at room temperature (up to 77°F [25°C]) for **a maximum of 30 days**. Keep it in its original carton to protect it from light.

After PRALUENT is removed from the refrigerator, it must be used within 30 days or thrown away.

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.

Please see Important Safety Information throughout document.

Please see full Prescribing Information available at PRALUENT.com.

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

Frequently Asked Questions

Taking PRALUENT® (alirocumab)

How do I take PRALUENT?

For more information on how to use PRALUENT, click here. You can also click below for the Instructions for Use.

Learn how to inject at home

- Do not try to inject PRALUENT until you have been shown how to do so by your healthcare provider or nurse. If your healthcare provider decides that you or your caregiver can give the injections of PRALUENT, he or she should give you training on the right way to do it
- 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
- Use PRALUENT exactly as your healthcare provider tells you to use it. Your healthcare provider will prescribe the dose that is best for you
- For a refresher on how to inject, check out our How to use PRALUENT page, or watch the instructional video at https://www.praluent.com/how-to-use-praluent/#inject. You can also download the detailed "Instructions for Use" (75 mg or 150 mg) to use as a guide

Follow your dosage schedule

- Depending on your dose, you will inject PRALUENT under your skin every 2 to 4 weeks (monthly)
- If your healthcare provider prescribes you the monthly dose, you will give yourself 2 separate injections in a row. Use a different pen for each injection, and inject in 2 different spots on your body to avoid irritation
- If you are taking other injectable medicines along with PRALUENT, do not inject PRALUENT in the same spot that you inject those other medicines
- Before each injection, check the label of your pen to make sure you have the correct medicine and the correct dose of PRALUENT
- See the next page if you miss a dose

Know what to do if you take too much PRALUENT

- If you use more PRALUENT than you should, talk to your healthcare provider or pharmacist

IMPORTANT: Do not stop using PRALUENT without talking with your healthcare provider. If you stop using PRALUENT, your cholesterol levels can increase.

What are the different doses for PRALUENT?

PRALUENT is available in 2 different dosage strengths, including 75 mg or 150 mg injected under the skin (subcutaneously). Dosage options include 75 mg or 150 mg every 2 to 4 weeks or 300 mg every 4 weeks (monthly) depending on your diagnosis and how PRALUENT was prescribed by your healthcare provider.

How often do I need to take PRALUENT?

Your healthcare provider will instruct you to inject PRALUENT under your skin every 2 weeks or 4 weeks (monthly).
Learn more about taking PRALUENT here.

Taking PRALUENT continues on next page

Important Safety Information (cont'd)

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

Please see Important Safety Information throughout document.

Please see full Prescribing Information available at PRALUENT.com.

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

Frequently Asked Questions

Taking PRALUENT® (alirocumab) (continued)

I forgot to take a dose. What should I do?

If you miss an every-2-weeks dose at your regular time	If you miss an every-4-weeks dose
Inject PRALUENT as soon as possible within 7 days of the missed dose. You may then resume your regular schedule. If you do not administer the dose within 7 days of your scheduled date, wait until the next dose on the original schedule.	Inject as soon as possible within 7 days of the missed dose. You may then resume your original schedule. If you do not administer the missed dose within 7 days, inject the dose immediately and start a new schedule based on the new date.

If you are not sure when to restart PRALUENT, ask your healthcare provider or pharmacist.

What should I do if the needle is bent or the pen is damaged?

If your PRALUENT needle or pen is bent or damaged in any way, do not use or try to fix it. You can call **1-844-PRALUENT (1-844-772-5836)** to report a product complaint. If you are having difficulty using your pen, please call your doctor.

Can I reuse the pen?

No. You must NOT reuse your PRALUENT pen. Once you have used the pen, throw it away in a sharps disposal container or a puncture-resistant container.

Important Safety Information (cont'd)

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

Please see Important Safety Information throughout document.

Please see full Prescribing Information available at PRALUENT.com.

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

Frequently Asked Questions

Storing PRALUENT® (alirocumab)

How should I store PRALUENT?

- Keep PRALUENT refrigerated at 36°F–46°F (2°C–8°C) in the outer carton in order to protect it from light until you are ready to use it
- **DO NOT** freeze PRALUENT
- **DO NOT** expose PRALUENT to extreme heat
- **DO NOT** shake PRALUENT
- Take your PRALUENT pen out of the refrigerator 30–40 minutes before you use it so that it can warm up
- **DO NOT heat the pen to warm it up**
- If needed, PRALUENT may be kept at room temperature (up to 77°F [25°C]) **for a maximum of 30 days**. Keep it in its original carton to protect it from light
- **DO NOT** store PRALUENT above 77°F (25°C)
- After PRALUENT is removed from the refrigerator, it must be used within 30 days or thrown away
- Keep PRALUENT and all medicines out of the reach of children

Can I still use PRALUENT if it has been out of the refrigerator for longer than 30 days?

No. **DO NOT** use any PRALUENT pens that have been left out of the refrigerator for more than 30 days. Keep PRALUENT and all medicines out of the reach of children.

Can I travel on a plane with my PRALUENT?

Check with your airline before you travel with PRALUENT. They can tell you if you may carry PRALUENT onto the airplane.

If you are allowed, keep PRALUENT in your carry-on. The temperature in the checked luggage area can sometimes be too hot or too cold.

Be sure to bring your PRALUENT medical documentation to show to airport security. Let the screener know if you have your medicine or a sharps disposal container in your carry-on.

Important Safety Information (cont'd)

Talk to your healthcare provider 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.

Please see Important Safety Information throughout document.

Please see full Prescribing Information available at PRALUENT.com.

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

Frequently Asked Questions

Proper Disposal

What do I do with the pen after I use it?

Once you have used your PRALUENT pen, throw it away in a sharps disposal container or a puncture-resistant container. **DO NOT** reuse the pen. Each state has different sharps disposal guidelines.

Patients taking PRALUENT are entitled to 2 sharps disposal containers per calendar year at no cost through MyPRALUENT®. To request your sharps disposal container, call **1-844-PRALUENT (1-844-772-5836)**. Each container typically holds over one year's usage of PRALUENT pre-filled pens. In the event that your sharps disposal container is destroyed, lost, or broken, a third sharps disposal container may be requested.

To learn more about the rules in your state, visit www.fda.gov/safesharpsdisposal. **DO NOT** throw away your used sharps disposal container in your household trash unless allowed by local law.

For California residents, the law prohibits disposal of home-generated sharps waste in the trash or recycling containers. For more information about sharps disposal, visit the CalRecycle website.

Important Safety Information (cont'd)

You may report side effects to the FDA at 1-800-FDA-1088.

Please see Important Safety Information throughout document.

Please see full Prescribing Information available at PRALUENT.com.

REGENERON®

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