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Praluent

Praluent 49

Pronunciation: PRAHL-u-ent Generic name: alirocumab

Dosage form: Prefilled pen (autoinjector) for subcutaneous use

Drug class: PCSK9 inhibitors

Medically reviewed by Carmen Pope, BPharm. Last updated on Mar 12, 2024.

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What is Praluent?

Praluent (alirocumab) is an injectable medicine that is given under your skin (subcutaneously) which may be used in adults with:

- cardiovascular disease to reduce the risk of heart attack, stroke, and certain types of chest pain conditions (unstable angina) that would normally require hospitalization
- high blood cholesterol (also called primary hyperlipidemia) including an inherited type of high cholesterol called heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C) or bad cholesterol together with dietary changes. Praluent can be used alone or in addition to other cholesterol-lowering medicines
- another inherited type of high cholesterol called homozygous familial hypercholesterolemia, who require additional lowering of their LDL-C.

Praluent may also be used in children aged 8 years and older with HeFH to reduce LDL-C, alongside dietary changes and other LDL-lowering treatments.

Praluent works by helping your liver reduce levels of "bad" cholesterol (low-density lipoprotein, or LDL) circulating in your blood. It does this by blocking the effects of the PCSK9 enzyme, which is an enzyme that binds to LDL receptors preventing LDL from being removed from the blood. This results in more receptors being available to remove LDL from the blood, which decreases LDL blood levels.

Praluent was first FDA-approved on July 24, 2015.

Warnings

Hypersensitivity reactions including inflammation of the blood vessels (vasculitis), swelling under the skin (angioedema), and other allergic reactions requiring hospitalization, have been reported with Praluent. Discontinue Praluent and tell your healthcare provider right away if you have an allergic reaction.

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).

Before taking this medicine

You should not use Praluent if you are allergic to alirocumab, Praulent, or any of the inactive ingredients in the injection.

Pregnancy and breastfeeding

It is not known if Praluent will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking Praluent, you are encouraged to call Regeneron at 1-844-734-6643 to share information about the health of you and your baby.

It is not known whether Praluent passes into breast milk or if it could harm a nursing baby. You should not breastfeed while using it.

Praluent pregnancy and breastfeeding warnings (more detail)

How should I use Praluent?

Use Praluent exactly as your healthcare provider tells you to use it.

- Praluent comes as a single-dose (1 time) pre-filled pen (autoinjector). Your healthcare provider will prescribe the
 dosage that is best for you.
- Praluent is injected under the skin (subcutaneously) every 2 weeks or every 4 weeks (monthly).
- Do not shake this medicine. Prepare an injection only when you are ready to give it. Do not use it if the medicine has changed color or has particles in it. Call your pharmacist for new medicine.
- Take the medicine out of the refrigerator and allow it to reach room temperature for 30 to 40 minutes before injecting
 your dose. Do not heat an injection pen or prefilled syringe, and do not leave the pen at room temperature for longer
 than 30 days.
- You can inject the medicine just under the skin of your upper thigh or abdomen (but keep at least 2 inches away from your belly button), or a caregiver can give it to you into the outer area of your upper arm.
- Each injection pen or prefilled syringe is for one use only. Throw it away after one use in a puncture-proof "sharps" container, even if there is still medicine left inside. Follow state or local laws about how to dispose of this container. Keep it out of the reach of children and pets.

Praluent is only part of a complete treatment program that also includes diet, statin medication, and regular blood testing. Follow your doctor's instructions very closely.

Further administration instructions

If your healthcare provider prescribes you the monthly dose, give 2 separate injections in a row, using a different pen for each injection and 2 different injection sites.

- Do not inject it with other injectable medicines at the same injection site.
- Always check the label of your pen to make sure you have the correct medicine and the correct dose

- If your healthcare provider decides that you or a caregiver can give the injections of Praluent, you or your caregiver should receive training on the right way to prepare and give it.
- Do not try to inject Praluent until you have been shown the right way by your healthcare provider or nurse.
- In children aged 12 to 17 years, Praluent should be given by or under the supervision of an adult.
- In children aged 8 to 11 years, Praluent should be given by a caregiver.

Do not stop using Praluent without talking with your healthcare provider. If you stop using it, your cholesterol levels can increase.

Praluent patient tips (more detail)

Praluent dosing information

Follow all your healthcare provider's instructions.

- The LDL-C lowering effect may be measured as early as 4 weeks after initiating therapy.
- In some patients, LDL-C can vary considerably during 4-week dosing intervals, therefore measure LDL-C just before
 the next scheduled dose.

Usual Adult Dose for Hyperlipidemia or Heterozygous Familial Hypercholesterolemia

- 75 mg SC every 2 weeks OR 300 mg SC once every 4 weeks
- May be adjusted up to 150mg SC every 2 weeks with an inadequate LDL-C (low-density lipoprotein) response.
- Maximum dose: 150 mg SC every 2 weeks.

Usual Adult Dose for Heterozygous Familial Hypercholesterolemia (HeFH) undergoing LDL Apheresis

- 150 mg SC once every 2 weeks; dose may be administered without regard to the timing of apheresis
- Detailed Praluent dosage information

What happens if I miss a dose?

If you forget to use Praluent or are not able to take the dose at your regular time, inject your missed dose as soon as you remember, within 7 days.

Then, if you inject every 2 weeks take your next dose in 2 weeks from the day you missed your dose or if you inject
every 4 weeks take your next dose in 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 and you inject every 2 weeks wait until your next scheduled dose to restart Praluent or if you inject every 4 weeks start a new schedule from the time you remember to take your dose.

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

What happens if I overdose?

What happens if I miss a dose?

Give an injection within 7 days after the missed dose. Then give the next injection 2 to 4 weeks after the missed dose was due, to put you back on your regular injection schedule.

If you are more than 7 days late for an injection:

- If you inject every 2 weeks, skip the missed dose and use your next dose at the regular time.
- If you inject every 4 weeks, start a new schedule based on the date you used the missed injection.

Do not use two doses at one time.

What happens if I overdose?

If you use more Praluent than you should, talk to your healthcare provider or pharmacist or call the Poison Help line at 1-800-222-1222.

What should I avoid while using Praluent?

Do not inject Praluent into skin that is sunburned, infected, swollen, or otherwise irritated.

Praluent side effects

Praluent can cause serious side effects, including:

- allergic reactions. These 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:
 - o a severe rash
 - severe itching
 - redness or swelling of the face
 - o trouble breathing lips, throat, or tongue
 - · hives.

Common side effects of Praluent affecting more than 5% of patients include:

- redness, itching, swelling, pain, or tenderness at the injection site
- muscle pain
- flu or flu-like symptoms
- · muscle spasms
- diarrhea
- · bruising.

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.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



1 Praluent side effects (more detail)

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What other drugs will affect Praluent?

Other drugs may interact with alirocumab, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all other medicines you use.

i Praluent drug interactions (more detail)

Does Praluent interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Praluent
+
Enter a drug name
Add

Storage

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 nor expose the pen to extreme heat or direct sunlight.
- Do not shake.

Allow 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. Do not store above 77°F (25°C).
- If not used within 30 days it must be thrown away.

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

Ingredients

Active ingredients: alirocumab.

Inactive ingredients: histidine, polysorbate 20, sucrose, and Water for Injection, USP.

Manufacturer

Regeneron Pharmaceuticals, Inc.

Praluent Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for Praluent.

Praluent (alirocumab) - Regeneron Pharmaceuticals, Inc.

Formulation type	Strength
Autoinjector	150 mg/mL
Autoinjector	75 mg/mL
Pre-Filled Syringe	150 mg/mL Discontinued
Pre-Filled Syringe	75 mg/mL Discontinued

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References

1. FDA Product Label

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- Praluent prescribing information
- Alirocumab (AHFS Monograph)

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• High Cholesterol, Familial Heterozygous

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

্যু Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

9 years FDA approved 2015

User Reviews & Ratings

6.3 / 10

304 Reviews

Images

Praluent 75 mg/mL pre-filled pen



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