

Patient Information
PRALUENT® (PRAHL-u-ent)
(alirocumab)
injection, for subcutaneous use

What is PRALUENT?

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-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).

Who should not use PRALUENT?

Do not use PRALUENT if you are allergic to alirocumab or to any of the ingredients in PRALUENT. See the end of this leaflet for a complete list of ingredients in PRALUENT.

What should I tell my healthcare provider before using PRALUENT?

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. It is not known if PRALUENT will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking PRALUENT.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take PRALUENT or breastfeed. You should 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.

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

How should I use PRALUENT?

- **See the detailed "Instructions for Use" that comes with this Patient Information about the right way to prepare and give your PRALUENT injections.**
- 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.
- 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 PRALUENT. **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, 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.
- PRALUENT is injected under the skin (subcutaneously) every 2 weeks or every 4 weeks (monthly).
- 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 PRALUENT together 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 of PRALUENT before each injection.
- 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 re-start 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 re-start PRALUENT, ask your healthcare provider or pharmacist.
- If you use more PRALUENT than you should, talk to your healthcare provider or pharmacist.
- **Do not** stop using PRALUENT without talking with your healthcare provider. If you stop using PRALUENT, your cholesterol levels can increase.

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
 - hives
 - trouble breathing
 - redness
 - severe itching
 - swelling of the face, lips, throat or tongue

The common side effects of PRALUENT 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.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of PRALUENT.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use PRALUENT for a condition for which it was not prescribed. **Do not** give PRALUENT to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information summarizes the most important information about PRALUENT. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about PRALUENT that is written for health professionals.

For more information about PRALUENT, go to www.PRALUENT.com or call 1-844-PRALUENT (1-844-772-5836).

What are the ingredients in PRALUENT?

- Active ingredient: alirocumab
- Inactive ingredients: histidine, polysorbate 20, sucrose, and Water for Injection, USP.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: March 2024

US.PRA.24.03.0006