

Patient Information
PRALUENT® (PRAHL-u-ent)
(alirocumab)
Injection, for Subcutaneous Use

Rx Only

What is PRALUENT?

PRALUENT is an injectable prescription medicine called a PCSK9 inhibitor. PRALUENT is used along with diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL) or atherosclerotic heart problems, who need additional lowering of LDL cholesterol. The effect of PRALUENT on heart problems such as heart attacks, stroke, or death is not known. It is not known if PRALUENT is safe and effective in children.

Who should not use PRALUENT?

Do not use PRALUENT if you are allergic to alicrocumab 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 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.

Pregnancy Registry. There is a pregnancy registry for women who take PRALUENT during pregnancy. The purpose of this registry is to collect information about your health and your baby's health. You can talk to your healthcare provider or contact 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/praluent/> to enroll in this registry or get more information.

- 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.

Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines you are taking or plan to take, including natural or herbal remedies.

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), or as a single-dose pre-filled syringe. Your healthcare provider will prescribe the type and 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 administer PRALUENT. **Do not** try to inject PRALUENT until you have been shown the right way by your healthcare provider or nurse.
- PRALUENT is injected under the skin (subcutaneously) every 2 weeks or every 4 weeks (monthly).
- If your healthcare provider prescribes you the monthly dose, you will give yourself 2 separate injections in a row, using a different syringe or pen for each injection and two different injection sites.
- **Do not** inject PRALUENT together with other injectable medicines at the same injection site.
- Always check the label of your pen or syringe 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. 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, severe itching, a swollen face, or trouble breathing.

The most common side effects of PRALUENT include: redness, itching, swelling, or pain/tenderness at the injection site, symptoms of the common cold, and flu or flu-like symptoms.

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: alicrocumab
- Inactive ingredients: histidine, polysorbate 20, sucrose, and water for injection.

Manufactured by: sanofi-aventis U.S. LLC, Bridgewater, NJ 08807; A SANOFI COMPANY, U.S. License # 1752; Marketed by sanofi-aventis U.S. LLC (NJ 08807) and Regeneron Pharmaceuticals, Inc. (NY 10591) / PRALUENT is a registered trademark of Sanofi / ©2018 Regeneron Pharmaceuticals, Inc. / sanofi-aventis U.S. LLC

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