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

PRALUENT®
THE FIRST U.S. FDA-APPROVED PCSK9 INHIBITOR

Praluent® (alirocumab) Injection is the first U.S. FDA-approved treatment in a new class of drugs known as PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitors. 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. For more information, visit www.Praluent.com.

EXECUTIVE SUMMARY

- Praluent is the first FDA-approved, subcutaneously-administered, human monoclonal antibody that targets PCSK9.
- Praluent works differently than currently available treatment options, including statins, and is indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical ASCVD, who require additional lowering of LDL cholesterol and continue to struggle to control their high LDL cholesterol, despite treatment with the current standard of care.
- Praluent is approved in two doses, 75 mg and 150 mg, that offer healthcare providers the flexibility to adjust treatment for individual patients' LDL cholesterol-lowering needs. The recommended starting dose for Praluent is 75 mg every two weeks.

DOSING

Praluent is available in two different doses (75 mg and 150 mg) that offer healthcare providers the flexibility to adjust treatment for individual patients' LDL cholesterol-lowering needs. The recommended starting dose for Praluent is 75 mg every two weeks. Both doses of Praluent are available in a single 1 milliliter (mL) injection delivered in a single-dose prefilled pen or syringe that patients self-administer every two weeks.

SAFETY AND EFFICACY

At both doses, Praluent provided significant reductions in LDL cholesterol. Praluent was well-tolerated in clinical trials when added to a statin. Injection site reactions were the most common events seen in clinical trials.

CLINICAL DATA

The FDA approval of Praluent was based on results from the Phase 3 ODYSSEY program – one of the most comprehensive clinical trial programs ever conducted for an investigational LDL cholesterol lowering therapy. In clinical trials, Praluent demonstrated significant LDL cholesterol reductions for both doses when added to maximally-tolerated doses of statins and was generally well tolerated.

INDICATION

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.

Please click here for full prescribing information.

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ALI-0880

IMPORTANT SAFETY INFORMATION

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

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.

PRALUENT can cause serious side effects, including 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.

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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full prescribing information.

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