**INDICATIONS AND USAGE**

- **PRALUENT** is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-cholesterol (LDL-C). (1.1)

**CONTRAINDICATIONS**

- History of a serious hypersensitivity reaction to PRALUENT. (4)

**WARNINGS AND PRECAUTIONS**

- Hypersensitivity reactions (e.g., pruritus, rash, urticaria), including some serious events (e.g., hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization), have been reported with PRALUENT treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with PRALUENT, treat according to the standard of care, and monitor until signs and symptoms resolve. (5.1)

**ADVERSE REACTIONS**

- The most commonly occurring adverse reactions (≥5% of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling Revised: 11/2018
**3 DOSAGE FORMS AND STRENGTHS**

PRALUENT is a clear, colorless to pale yellow solution available as follows:

- **Injection:** Single-dose pre-filled pen
  - 75 mg/mL
  - 150 mg/mL

**4 CONTRAINdicATIONS**

PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT. Reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization. [See Warnings and Precautions (5.1).]

**5 ADVERSE REACTIONS**

**6.1 Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of PRALUENT was evaluated in 9 placebo-controlled trials that included 2476 patients treated with PRALUENT 75 mg and/or 150 mg every 2 weeks, including 2135 exposed for 6 months and 1999 exposed for more than 1 year (median treatment duration of 65 weeks). The mean age of the population was 59 years, 40% of the population were female, 37% of all patients had a diagnosis of heterozygous familial hypercholesterolemia (0.7%) treated with PRALUENT 300 mg Q4W discontinued treatment due to local injection site reactions, had more reports of associated symptoms, and had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo.

In a 48-week placebo-controlled trial evaluating PRALUENT 75 mg and/or 150 mg every 4 weeks (Q4W), and 75 mg Q2W, in which all patients received an injection of drug or placebo every 2 weeks to maintain the blind, local injection site reactions were reported more frequently in patients treated with PRALUENT 300 mg Q4W as compared to those receiving PRALUENT 75 mg Q2W or placebo (16.6%, 9.6%, and 7.9%, respectively). Three patients (0.7%) treated with PRALUENT 300 mg Q4W discontinued treatment due to local injection site reactions versus no patients (0%) in the other 2 treatment groups.

**6.2 Immune Reactivity**

Because antibodies to all therapeutic proteins, there is a potential for immunogenicity with PRALUENT. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, collection, storage, and processing, and the underlying disease.

Adverse reactions reported in at least 2% of PRALUENT-treated patients, and more frequently than in placebo-treated patients are shown in Table 1.

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Placebo (N=1276)</th>
<th>PRALUENT* (N=2476)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>11.1%</td>
<td>11.3%</td>
</tr>
<tr>
<td>Injection site reactions†</td>
<td>5.1%</td>
<td>7.2%</td>
</tr>
<tr>
<td>Influenza</td>
<td>4.6%</td>
<td>5.7%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>4.6%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4.4%</td>
<td>4.7%</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>3.8%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Myalgie</td>
<td>3.4%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>2.4%</td>
<td>3.1%</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>2.7%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Cough</td>
<td>2.3%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Contusion</td>
<td>1.3%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Muscle/skeletal pain</td>
<td>1.6%</td>
<td>2.1%</td>
</tr>
</tbody>
</table>

†Includes erythema/redness, itching, swelling, pain/tenderness

Adverse reactions led to discontinuation of treatment in 5.3% of patients treated with PRALUENT and 5.1% of patients treated with placebo. The most common adverse reactions leading to treatment discontinuation in patients treated with PRALUENT were allergic reactions (0.6% versus 0.2% for PRALUENT and placebo, respectively) and elevated liver enzymes (0.3% versus <0.1%).

Local Injection Site Reactions

In a pool of placebo-controlled trials evaluating PRALUENT 75 mg and/or 150 mg administered every 2 weeks (Q2W), local injection site reactions including erythema/redness, itching, swelling, and pain/tenderness were reported more frequently in patients treated with PRALUENT (7.2% versus 5.1% for PRALUENT and placebo, respectively). Few patients discontinued treatment because of these reactions (0.2% versus 0.4% for PRALUENT and placebo, respectively), but patients receiving PRALUENT had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo.

In a 48-week placebo-controlled trial evaluating PRALUENT 300 mg every 4 weeks (Q4W) and 75 mg Q2W, in which all patients received an injection of drug or placebo every 2 weeks to maintain the blind, local injection site reactions were reported more frequently in patients treated with PRALUENT 300 mg Q4W as compared to those receiving PRALUENT 75 mg Q2W or placebo (16.6%, 9.6%, and 7.9%, respectively). Three patients (0.7%) treated with PRALUENT 300 mg Q4W discontinued treatment due to local injection site reactions versus no patients (0%) in the other 2 treatment groups.

**6.3 Postmarketing Experience**

The following adverse reactions have been reported during postapproval use of PRALUENT. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- General disorders and administration site conditions
- Flu-like illness

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

**Pregnancy Exposure Registry**

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to PRALUENT during pregnancy. Please contact 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/praluent/ to enroll in or to obtain information about the registry.

**Risk Summary**

There are no available data on use of PRALUENT in pregnant women to inform a drug-associated risk. In animal reproduction studies, there were no effects on embryo-fetal development when rats were subcutaneously administered alirocumab during organogenesis at dose exposures up to 12-fold the exposure at the maximum recommended human dose of 150 mg every two weeks. In monkeys, suppression of the humoral immune response to alirocumab was observed in infants when alirocumab was dosed during organogenesis to parturition at dose exposures 13-fold the exposure at the maximum recommended human dose of 150 mg every two weeks. No additional effects on pregnancy or neonatal/infant development were observed at dose exposures up to 81-fold the maximum recommended human dose of 150 mg every 2 weeks. In addition, alirocumab was detected in maternal milk at <0.1% of the maternal plasma concentrations were observed in the infant monkeys at birth at comparable levels to maternal serum, indicating that alirocumab, like other IgG antibodies, crosses the placental barrier. FDA’s experience with monoclonal antibodies in humans indicates that they are not transferred across the placenta in the first trimester; however, they are likely to cross the placenta in increasing amounts in the second and third trimester. Consider the benefits and risks of PRALUENT and possible risks to the fetus before prescribing PRALUENT to pregnant women.
In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

Data

Animal data

In Sprague Dawley rats, no effects on embryo-fetal development were observed when alirocumab was dosed at up to 75 mg/kg, whereas the subcutaneous route on gestation days 6 and 12 at exposures 12-fold the maximum recommended human dose of 150 mg every two weeks, based on serum AUC.

In cynomolgus monkeys, suppression of the humoral immune response to keyhole limpet hemocyanin (KLH) antigen was observed in infant monkeys at 4 to 6 months of age when alirocumab was dosed during organogenesis to parturition at 15 mg/kg/week and 75 mg/kg/week by the subcutaneous route, corresponding to 13-fold and 81-fold the human exposure at the maximum recommended human dose of 150 mg every two weeks, based on serum AUC. The lowest dose tested in the monkey resulted in humoral immune suppression; therefore it is unknown if this effect would be observed at clinical exposure. No study designed to challenge the immune system of infant monkeys was conducted. No additional embryo-fetal, prenatal or postnatal effects were observed in infant monkeys, and no maternally mediated effects were observed, when alirocumab was dosed at up to 75 mg/kg/week by the subcutaneous route, corresponding to maternal exposure of 81-fold the exposure at the maximum recommended human dose of 150 mg every two weeks, based on serum AUC.

8.2 Lactation

Risk Summary

There is no information regarding the presence of alirocumab in human milk, the effects on the breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother’s clinical need for PRALUENT and any potential adverse effects on the breastfed infant from PRALUENT or from the underlying maternal condition. Human IgG is present in human milk, but published data suggest that breastmilk IgG antibodies do not enter the neonatal and infant circulation in substantial amounts.

8.4 Pediatric Use

Safety and efficacy in pediatric patients have not been established.

8.5 Geriatric Use

In controlled studies, 1158 patients treated with PRALUENT were ≥65 years of age and 241 patients treated with PRALUENT were ≥75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Renal Impairment

No dose adjustment is needed for patients with mild or moderately impaired renal function. No data are available in patients with severe renal impairment. [See Clinical Pharmacology (12.3)].

8.7 Hepatic Impairment

No dose adjustment is needed for patients with mild or moderate hepatic impairment. No data are available in patients with severe hepatic impairment. [See Clinical Pharmacology (12.3)].

11 DESCRIPTION

Alirocumab is a human monoclonal antibody (IgG1 isotype) that targets proprotein convertase subtilisin kexin type 9 (PCSK9). Alirocumab is a PCSK9 inhibitor produced by recombinant DNA technology in Chinese Hamster Ovary cell suspension culture. Alirocumab consists of two disulfide-linked human heavy chains, each covalently linked to a human kappa light chain. The heavy chain has a variable domain, combining to form the PCSK9 binding site within the antibody. Alirocumab has an approximate molecular weight of 146 kDa. PRALUENT is a sterile, preservative-free, clear, colorless to pale yellow solution for subcutaneous administration. Each 75 mg/mL pre-filled pen or pre-filled syringe contains 75 mg alirocumab, histidine (8 mg/mL), polysorbate 20 (0.1 mg/mL), sucrose (100 mg), and Water for Injection USP, to pH 6.0. Each 150 mg/mL pre-filled pen or pre-filled syringe contains 150 mg alirocumab, histidine (8 mg/mL), polysorbate 20 (0.1 mg/mL), sucrose (100 mg), and Water for Injection USP, to pH 6.0.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Alirocumab is a human monoclonal antibody that binds to proprotein convertase subtilisin kexin type 9 (PCSK9). PCSK9 binds to the low-density lipoprotein receptors (LDLR) on the surface of hepatocytes to promote LDLR degradation within the liver. LDLR is the primary receptor that clears circulating LDL, therefore the decrease in LDLR levels by PCSK9 results in higher blood levels of LDL-C. By inhibiting the binding of PCSK9 to primary receptor that clears circulating LDL, therefore the decrease in LDLR levels by alirocumab was observed in infant monkeys at 4 to 6 months of age when the antibody was dosed during organogenesis to parturition at 15 mg/kg/week and 75 mg/kg/week by the subcutaneous route, corresponding to 13-fold and 81-fold the human exposure at the maximum recommended human dose of 150 mg every two weeks, based on serum AUC.

Two elimination phases were observed for alirocumab. At low concentrations, the elimination is predominately through saturable binding to target (PCSK9), while at higher concentrations the elimination of alirocumab is largely through a non-saturable proteolytic pathway.

Based on a population pharmacokinetic analysis, the median apparent half-life of alirocumab at steady state was 17 to 20 days in patients receiving alirocumab at subcutaneous doses of 75 mg Q2W or 150 mg Q2W.

Specific Populations

A population pharmacokinetic analysis was conducted on data from 2799 subjects. Age, body weight, gender, race, and creatinine clearance were found not to significantly influence alirocumab pharmacokinetics. No dose adjustments are recommended for these demographics.

Pediatric

PRALUENT has not been studied in pediatric patients [see Use in Specific Populations (8.4)]

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies have not been conducted with alirocumab. The mutagenic potential of alirocumab has not been evaluated; however, monoclonal antibodies are not expected to alter DNA or chromosomes. There were no adverse effects on surrogate markers of fertility (e.g., estrous cyclicity, testicular volume, ejaculate volume, sperm motility, or total sperm count per ejaculate) in a 6-month chronic toxicology study in sexually-mature monkeys subcutaneously administered at 5, 15, and 75 mg/kg/week at systemic exposures up to 103-fold the 150 mg every 2 weeks subcutaneous clinical dose based on serum AUC. In addition, there were no adverse alirocumab-related anatomic pathology or histopathology findings in reproductive tissues in rat or monkey toxicology studies at systemic exposures up to 11-fold and 103-fold respectively, in the 6-month studies, compared to clinical systemic exposure following a 150 mg every 2 weeks dose on serum AUC.

13.2 Animal Toxicology and/or Pharmacology

During a 13-week toxicology study of 75 mg/kg once weekly alirocumab in combination with 40 mg/kg once daily atorvastatin in adult monkeys, there were no effects of alirocumab on reproductive endpoints, immune function, or on the breastfed infant, or the effects on milk production. The development and health of breastfed infants was not altered by alirocumab. No data are available in patients with severe hepatic impairment.

Hepatic impairment

Following administration of a single 75 mg SC dose, alirocumab pharmacokinetic profiles in subjects with mild and moderate hepatic impairment were similar to those in subjects with normal hepatic function. No data are available in patients with severe hepatic impairment.

Drug-Drug Interactions

The median apparent half-life of alirocumab is reduced to 12 days when administered with a statin; however, this difference is not clinically meaningful and does not impact dosing recommendations.

14 CLINICAL STUDIES

The efficacy of PRALUENT was investigated in five double-blind placebo-controlled trials that enrolled 3499 patients; 36% were patients with heterozygous familial hypercholesterolemia (HeFH) and 54% were non-FH patients who had clinical atherosclerosis cardiovascular disease. Three of the five trials were conducted exclusively in patients with HeFH; 85% of patients were treated with 100 mg every 2 weeks subcutaneous clinical dose based on serum AUC. In addition, there were no studies designed to challenge the immune system of infant monkeys was conducted. No additional embryo-fetal, prenatal or postnatal effects were observed in infant monkeys, and no maternally mediated effects were observed, when alirocumab was dosed at up to 75 mg/kg/week by the subcutaneous route, corresponding to maternal exposure of 81-fold the exposure at the maximum recommended human dose of 150 mg every two weeks, based on serum AUC.

After subcutaneous administration of alirocumab 75 or 150 mg, maximal suppression of free LDL-C levels.

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and required additional LDL-C reduction. The mean age was 61 years (range 18–89), 38% were women, 93% were Caucasian, 3% were Black, and 5% were Hispanic/Latino. Overall, 69% were non-HF patients with clinical atherosclerotic cardiovascular disease and 18% had HeFH. The average LDL-C at baseline was 122 mg/dL. The proportion of patients who prematurely discontinued study drug prior to the 24-week endpoint was 8% among those treated with PRALUENT and 8% among those treated with placebo. At week 24, the treatment difference between PRALUENT and placebo in mean LDL-C percent change was -58% (95% CI: -61%, -56%; p-value <.0001). For additional results see Table 2 and Figure 1.

Table 2: Mean Percent Change from Baseline and Difference* from Placebo in Lipid Parameters at Week 24 in Study 1†

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>LDL-C</th>
<th>Total-C</th>
<th>Non-HDL-C</th>
<th>Apo B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>PRALUENT (150 mg)</td>
<td>-58</td>
<td>-36</td>
<td>-49</td>
<td>-50</td>
</tr>
</tbody>
</table>

*Difference is PRALUENT minus Placebo
†A pattern-mixture model approach was used with multiple imputation of missing post-treatment values based on a subject's own baseline value and multiple imputation of missing on-treatment values based on a model including available on-treatment values
‡Dose was up-titrated to 150 mg Q2W in 196 (42%) patients treated for at least 12 weeks considering both trials together. The proportion of patients who prematurely discontinued study drug prior to the 24-week endpoint was 6% among those treated with PRALUENT and 4% among those treated with placebo. At week 12, the treatment difference between PRALUENT 75 mg Q2W and placebo in mean LDL-C percent change was -48% (95% CI: -52%, -44%). At week 12, if additional LDL-C lowering was required based on pre-specified LDL-C criteria, PRALUENT was up-titrated to 150 mg Q2W for the remainder of the trials. The dose was up-titrated to 150 mg Q2W in 196 (42%) of 469 patients treated with PRALUENT for at least 12 weeks. At week 24, the mean treatment difference between PRALUENT and placebo in mean LDL-C percent change from baseline was -54% (95% CI: -59%, -50%; p-value <.0001). The LDL-C-lowering effect was sustained to week 52. For additional results see Table 3 and Figure 2.

Table 3: Mean Percent Change from Baseline and Difference* from Placebo in Lipid Parameters at Week 12 and Week 24 in Patients with HeFH (Studies 3 and 4 Pooled)†

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>LDL-C</th>
<th>Total-C</th>
<th>Non-HDL-C</th>
<th>Apo B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>PRALUENT (75 mg)</td>
<td>-47</td>
<td>-30</td>
<td>-42</td>
<td>-40</td>
</tr>
</tbody>
</table>

*Difference is PRALUENT minus Placebo
†A pattern-mixture model approach was used with multiple imputation of missing post-treatment values based on a subject's own baseline value and multiple imputation of missing on-treatment values based on a model including available on-treatment values
‡Dose was up-titrated to 150 mg Q2W in 196 (42%) patients treated for at least 12 weeks.

Figure 1: Mean Percent Change from Baseline in LDL-C Over 52 Weeks in Patients on Maximally Tolerated Statin Treated with PRALUENT 150 mg Q2W and Placebo Q2W (Study 1)†

Figure 2: Mean Percent Change from Baseline in LDL-C Over 52 Weeks in Patients with HeFH on Maximally-Tolerated Statin Treated with PRALUENT 75/150 mg Q2W and Placebo Q2W (Studies 3 and 4 Pooled)†

Overall, 45% of these patients with HeFH also had clinical atherosclerotic cardiovascular disease. The average LDL-C at baseline was 141 mg/dL. Considering both trials together, the proportion of patients who prematurely discontinued study drug prior to the 24-week endpoint was 6% among those treated with PRALUENT and 4% among those treated with placebo. At week 12, the treatment difference between PRALUENT 75 mg Q2W and placebo in mean LDL-C percent change was -48% (95% CI: -52%, -44%). At week 12, if additional LDL-C lowering was required based on pre-specified LDL-C criteria, PRALUENT was up-titrated to 150 mg Q2W for the remainder of the trials. The dose was up-titrated to 150 mg Q2W in 196 (42%) of 469 patients treated with PRALUENT for at least 12 weeks. At week 24, the mean treatment difference between PRALUENT and placebo in mean LDL-C percent change from baseline was -54% (95% CI: -59%, -50%; p-value <.0001). The LDL-C-lowering effect was sustained to week 52. For additional results see Table 3 and Figure 2.
Study 6 was a multi-center, double-blind, placebo-controlled trial that randomly assigned 312 patients to PRALUENT 300 mg Q4W, 78 patients to PRALUENT 75 mg Q2W, and 157 patients to placebo who had hypercholesterolemia and were taking concomitant statin. The mean age was 62 years (range 21–88), 37% were women, 88% were Caucasian, 10% were Black, and 2% were Hispanic/Latino. Of these, 64% of patients had clinical atherosclerotic cardiovascular disease and 8% had HeFH. The mean LDL-C at baseline was 113 mg/dL. The proportion of patients who discontinued study drug prior to the 24-week endpoint was 9% among those treated with PRALUENT 300 mg Q4W, 13% among those treated with PRALUENT 75 mg Q2W and 13% among those treated with placebo. At week 12, the treatment difference between PRALUENT 300 mg Q4W and placebo in mean percent change in LDL-C from baseline was -54% (97.5% CI: -61%, -46%), and the treatment difference between PRALUENT 75 mg Q2W and placebo in mean percent change in LDL-C was -44% (97.5% CI: -53%, -35%) (Figure 3).

Figure 3: Mean Percent Change from Baseline in LDL-C up to Week 12 in Patients on Concomitant Statin Treated with PRALUENT 75 mg Q2W, PRALUENT 300 mg Q4W or Placebo

*The means were estimated based on all randomized patients, with multiple imputation of missing data taking into account treatment adherence.

At week 12, if additional LDL-C lowering was required based on pre-specified LDL-C criteria, PRALUENT was adjusted to 150 mg Q2W for the remainder of the trial. The dose was adjusted to 150 mg Q2W in approximately 20% of patients treated with PRALUENT 75 mg Q2W or 300 mg Q4W for at least 12 weeks. At week 24, the treatment difference between initial assignment to PRALUENT 300 mg Q4W and placebo in mean percent change in LDL-C from baseline was -56% (97.5% CI: -62%, -49%; p-value: <0.0001), and the treatment difference between initial assignment to PRALUENT 75 mg Q2W and placebo in mean percent change in LDL-C from baseline was -46% (97.5% CI: -57%, -38%).

Study 7 was a multicenter, double-blind, placebo-controlled trial that randomly assigned patients with HeFH who were undergoing LDL apheresis to PRALUENT 150 mg Q2W (N=41) or placebo (N=21). Patients were treated in combination with their usual LDL apheresis schedule for 6 weeks. The mean age was 73 years (range 27–79), 42% were women, 97% were Caucasian, 3% were Black, and 0% were Hispanic/Latino. The mean LDL-C at baseline, measured before the apheresis procedure, was 181 mg/dL. The proportion of patients who discontinued study drug prior to the 6-week endpoint was 2% among those treated with PRALUENT 150 mg Q2W and 5% among those treated with placebo. At week 6, the mean percent change from baseline in pre-apheresis LDL-C was -53% in patients in the PRALUENT group compared to 1% in patients who received placebo.

16 HOW SUPPLIED/STORAGE AND HANDLING

PRALUENT is a clear, colorless to pale yellow solution, supplied in single-dose pre-filled pens and single-dose pre-filled glass syringes. Each pre-filled pen or pre-filled syringe of PRALUENT is designed to deliver 1 mL of 75 mg/mL or 150 mg/mL solution. PRALUENT is available in cartons containing 1 or 2 pre-filled pens and 1 or 2 pre-filled syringes.

### Pack Size

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>75 mg/mL Pre-filled Pen</th>
<th>150 mg/mL Pre-filled Pen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pack of 1 pen</td>
<td>NDC 0024-5901-01</td>
<td>NDC 0024-5902-01</td>
</tr>
<tr>
<td>Pack of 2 pens</td>
<td>NDC 0024-5901-02</td>
<td>NDC 0024-5902-02</td>
</tr>
</tbody>
</table>

### Pack Size

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>75 mg/mL Pre-filled Syringe</th>
<th>150 mg/mL Pre-filled Syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pack of 1 syringe</td>
<td>NDC 0024-5903-01</td>
<td>NDC 0024-5904-01</td>
</tr>
<tr>
<td>Pack of 2 syringes</td>
<td>NDC 0024-5903-02</td>
<td>NDC 0024-5904-02</td>
</tr>
</tbody>
</table>

**Storage**

Store in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton in order to protect from light.