Praluent® ▼(alirocumab)

Prescribing Information

Please refer to the Praluent Summary of Product Characteristics for full prescribing details. **Presentation:** Single-use pre-filled pen or syringe containing 75 mg or 150 mg Alirocumab in 1 ml solution. Alirocumab is a human IgG1 monoclonal antibody produced in Chinese Hamster Ovary cells by recombinant DNA technology. **Indications:** Praluent is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin; or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. **Dosage and Administration:** The usual starting dose for Praluent is 75 mg administered subcutaneously once every 2 weeks. Patients requiring larger LDL-C reduction (>60%) may be started on 150 mg administered subcutaneously once every 2 weeks. If a dose is missed, the patient should administer the injection as soon as possible and thereafter resume treatment two weeks from the day of the missed dose. Lipid levels can be assessed 4 weeks after treatment initiation or titration, when steady-state LDL C is usually achieved, and dose adjusted if required. Praluent is injected as a subcutaneous injection into the thigh, abdomen or upper arm. Praluent should not be injected into areas of active skin disease or injury such as sunburns, skin rashes, inflammation, or skin infections. Praluent must not be co-administered with other injectable medicinal products at the same injection site. The patient may either self-inject Praluent, or a caregiver may administer Praluent, after guidance has been provided by a healthcare professional on proper subcutaneous injection technique. Praluent should be allowed to warm to room temperature for 30 to 40 minutes prior to use. ***Elderly*****:** No dose adjustment needed ***Children***: The safety and efficacy of Praluent in children and adolescents less than 18 years of age have not been established. No data are available. ***Hepatic impairment*****:** No dose adjustment is needed for patients with mild or moderate hepatic impairment. Patients with severe hepatic impairment (Child-Pugh C) have not been studied. Praluent should be used with caution in patients with severe hepatic impairment. ***Renal impairment:*** No dose adjustment is needed for patients with mild or moderate renal impairment. In clinical studies, there was limited representation of patients with severe renal impairment (defined as eGFR < 30 mL/min/1.73 m^2). Praluent should be used with caution in patients with severe renal impairment. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients. **Precautions and Warnings**: General allergic reactions, including pruritus, as well as rare and sometimes serious allergic reactions such as hypersensitivity, nummular eczema, urticaria, and hypersensitivity vasculitis have been reported in clinical studies. If signs or symptoms of serious allergic reactions occur, treatment with Praluent must be discontinued and appropriate symptomatic treatment initiated. **Interactions**: Since alirocumab is a biological medicinal product, no pharmacokinetic effects of alirocumab on other medicinal products and no effect on cytochrome P450 enzymes are anticipated. **Pregnancy and Lactation:** There are no data from the use of Praluent in pregnant women. Alirocumab is an IgG1 antibody and is expected to cross the placental barrier. The use of Praluent is not recommended during pregnancy unless the clinical condition of the patient warrants it. Praluent is not recommended in breast-feeding women when colostrum is produced; for the rest of the breast-feeding period, a decision should be made whether to discontinue nursing or to discontinue Praluent. **Fertility:** In animal studies, there were no

adverse effects on surrogate markers of fertility. There are no data on adverse effects on fertility in humans.

For full information on Adverse Events please consult the Praluent Summary of Product Characteristics.

Adverse Reactions: Common (≥1/100 to <1/10) adverse reactions in pooled controlled studies were local injection site reactions (including erythema/redness, itching, swelling, pain/tenderness), upper respiratory tract signs and symptoms (including mainly oropharyngeal pain, rhinorrhoea, sneezing), and pruritus. The most common adverse reactions leading to treatment discontinuation in patients treated with Praluent were local injection site reactions. Most injection site reactions were transient and of mild intensity. General allergic reactions were reported more frequently in the Praluent group than in the control group, mainly due to a difference in the incidence of pruritus. The observed cases of pruritus were typically mild and transient. Rare (≥1/10,000 to <1/1,000) and sometimes serious allergic reactions such as hypersensitivity, hypersensitivity vasculitis, urticaria, and eczema nummular have been reported in controlled clinical studies. No difference in the safety profile was observed between the 75 mg and 150 mg doses used in the phase III program.
Special precautions for storage: Store in a refrigerator (2°C to 8°C). Do not freeze. Time out of refrigeration should not exceed a maximum of 24 hours at temperatures below 25°C. Keep the pen in the outer carton in order to protect from light.
Package Quantities and Basic NHS Price: Pack of 1 pre-filled pen of 75 or 150 mg/ml: £168. Pack of 2 pre-filled pens of 75 or 150 mg/ml: £336. **Legal Category:** POM. **Marketing Authorisation Numbers**: 1x 75 mg: EU/1/15/1031/001, 2x 75 mg: EU/1/15/1031/002, 1x 150 mg: EU/1/15/1031/007, 2x 150 mg: EU/1/15/1031/008. **Marketing Authorisation Holder:** sanofi-aventis groupe, 54 rue La Boétie, F - 75008 Paris, France. **Further information is available from:** Medical Information Department, Sanofi, One Onslow Street, Guildford, GU1 4YS, Tel; 0845 372 7101
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to the Sanofi drug safety department on 01483 55 4242