Prescribing Information: Praluent® (Alirocumab) solution for injection in pre-filled pen

Please refer to the Summary of Product Characteristics (SmPC) for full prescribing details.

Presentations: Praluent 75mg or 150mg solution for injection in pre-filled pen, contains 75mg Alirocumab in 1ml solution or 150mg Alirocumab in 1ml solution, respectively.

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. Praluent is indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies 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: Secondary causes of hyperlipidaemia or mixed dyslipidaemia (e.g. nephrotic syndrome, hypothyroidism) should be excluded prior to initiation of Alirocumab. The usual starting dose is 75mg, once every 2 weeks. Patients requiring larger LDL-C reduction (>60%) may be started on 150mg once every 2 weeks or 300mg once every 4 weeks (monthly). A dose of 300mg should be given as two 150mg injections consecutively at two different injection sites. If a dose is missed, the dose should be administered as soon as possible and thereafter, dosing should be resumed on the original schedule. Lipid levels can be assessed 4 – 8 weeks after treatment initiation or titration, and dose adjusted accordingly (up-titration or down-titration). If additional LDL-C reduction is needed in patients treated with 75mg once every 2 weeks or 300mg once every 4 weeks (monthly), the dosage may be adjusted to the maximum dosage of 150mg once every 2 weeks. For dosing schedule and method of administration in children >8 years, please consult the SmPC. Praluent should be given by a caregiver in children less than 12 years of age and for adolescents 12 years or older, Praluent should be administered by or under adult supervision. **Method of administration:** Praluent is injected as a subcutaneous injection into the thigh, abdomen or upper arm. It is recommended to rotate the injection site with each injection. Alirocumab should not be injected into areas of active skin disease or injury such as sunburns, skin rashes, inflammation, or skin infections. Alirocumab 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. The solution should be allowed to warm to room temperature for 30 – 40 minutes prior to use.

Special populations: Elderly and body weight impact: No dose adjustment needed. Hepatic impairment: No dose adjustment is needed for patients with mild or moderate hepatic impairment. Alirocumab should be used with caution in patients with severe hepatic impairment (Child-Pugh C). Renal impairment: No dose adjustment is needed for patients with mild or moderate renal impairment. Alirocumab should be used with caution in patients with severe renal impairment. Paediatric population: The safety and efficacy of Praluent in children less than 8 years of age have not been established.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Precautions and Warnings: Allergic reactions: 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. Angioedema has been reported. If signs or symptoms of serious allergic reactions occur, treatment with alirocumab 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. Statins and other lipid lowering therapies can increase clearance of Praluent; however, LDL-C reduction was maintained on two weekly Alirocumab administrations.

Fertility, Pregnancy and Breast-feeding: 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. Thus 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. There are no data on adverse effects on fertility in humans.

Adverse Reactions: Common: local injection site reactions (including erythema/redness, itching, swelling, pain/ tenderness), upper respiratory tract signs and symptoms (oropharyngeal pain, rhinorrhoea, sneezing), and pruritus. Rare: Hypersensitivity, hypersensitivity vasculitis, urticaria and eczema nummular. Not known: Flu-like illness, angioedema. *Prescribers should consult the SmPC in relation to other adverse reactions.*

Legal Category: POM.

NI List price: 2 x 75mg or 150mg: £336.

Marketing Authorisation Numbers: 2 x 75mg: EU/1/15/1031/002; 2 x 150mg: EU/1/15/1031/008.

Marketing Authorisation Holder: Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France. **For more information please contact:** Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 090 2314.
Alternatively, send via email to UK-drugsafety@sanofi.com