Praluent® (alirocumab) - Abbreviated Prescribing Information:

Praluent® 75 mg in 1ml solution for injection in pre-filled pen; Praluent® 150 mg in 1ml solution for injection in pre-filled pen; Praluent® 300 mg in 2ml solution for injection in pre-filled pen. THERAPEUTIC 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. POSOLOGY AND METHOD OF ADMINISTRATION: Prior to initiating Praluent® secondary causes of hyperlipidaemia or mixed dyslipidaemia should be excluded. 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, or 300 mg once every 4 weeks (monthly), administered subcutaneously. Special populations: The safety and efficacy of Praluent® in children and adolescents less than 18 years of age have not been established. No data are available. No dose adjustment is needed for elderly patients, patients with mild or moderate hepatic impairment, patients with mild or moderate renal impairment, or based on weight. 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. Each pre-filled pen is for single use only. CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients listed in the full SmPC. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. 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 in the post-marketing setting. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Praluent® and initiate appropriate symptomatic treatment. Praluent® should be used with caution in patients with severe renal impairment and in patients with severe hepatic impairment. For further details on special warnings and precautions for use see full SmPC. DRUG 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: The use of Praluent® is not recommended during pregnancy. Since the effects of alirocumab on the breast-fed infant are unknown, a decision should be made whether to discontinue nursing or to discontinue Praluent® during this period. There are no data on adverse effects on fertility in humans. EFFECTS ON ABILITY TO DRIVE: Praluent® has no or negligible influence on the ability to drive and use machines. UNDESIRABLE EFFECTS: The most common adverse reactions, at recommended doses, are local injection site reactions (6.1%), upper respiratory tract signs and symptoms (2.0%), and pruritus (1.1%). Most common adverse reactions leading to treatment discontinuation in patients treated with alirocumab were local injection site reactions. The safety profile in patients treated with a 300 mg once every 4 week (monthly) dosing regimen was similar to the safety profile as described for the clinical studies program using a 2 week dosing regimen, except for a higher rate of local injection site reactions.

Local injection site reactions were reported overall at a frequency of 16.6% in the 300 mg once every 4 weeks treatment group and 7.9% in the placebo group. No difference in the safety profile was observed between the two doses (75 mg and 150 mg) used in the phase 3 program. For further details on adverse events please consult the full SmPC. OVERDOSE: There is no specific treatment for Praluent® overdose. In the event of an overdose, the patient should be treated symptomatically, and supportive measures instituted as required. SPECIAL PRECAUTIONS FOR STORAGE: Store in a refrigerator (2°C to 8°C). Do not freeze. Praluent can be stored outside the refrigerator (below 25 °C) protected from light for a single period not exceeding 30 days. After removal from the refrigerator, the medicinal product must be used within 30 days or discarded. Keep the pen in the outer carton in order to protect from light. PHARMACOLOGICAL PROPERTIES: Pharmacotherapeutic group: other lipid modifying agents; ATC code: C10AX14. LEGAL CATEGORY: Medicinal product subject to medical prescription. For further information kindly refer to the full SmPC dated November 2020