EMA/383130/2020
EMEA/H/C/00388

Praluent (*alirocumab)*

An overview of Praluent and why it is authorised in the EU

What is Praluent and what is it used for?

Praluent is a medicine for lowering levels of fat in the blood.

It is used to reduce fat levels in adults with primary hypercholesterolaemia (high levels of blood cholesterol without an identifiable cause, often resulting from the person's genetic makeup) and mixed dyslipidaemia (abnormal levels of different fats in the blood, including cholesterol).

It is also used to reduce the risk of heart problems and strokes in patients who have atherosclerotic cardiovascular disease (heart problems such as heart attack, stroke or other problems of the circulatory system caused by fatty deposits build up in the walls of the arteries).

Praluent is used in combination with a statin or a statin and other fat-lowering medicines. Praluent can also be used without a statin in patients who cannot take statins. Some patients are required to be on a low fat diet.

It contains the active substance alirocumab.

How is Praluent used?

Before starting treatment with Praluent, other causes of excess cholesterol and abnormal fat levels in the blood should be excluded. The medicine can only be obtained with a prescription.

Praluent is available as a solution for injection in a pre-filled syringe or pre-filled pen (75 mg, 150 mg and 300 mg). The injection is given under the skin of the abdomen, thigh or upper arm.

The usual starting dose is 75 mg every two weeks, but patients requiring bigger reductions of blood fat levels may start with 150 mg every two weeks or 300 mg every 4 weeks. The dose of Praluent is adjusted based on the levels of fats in blood and response to the medicine. If the desired response is not achieved after 4 to 8 weeks of treatment, the doctor can increase or decrease the dose.

Patients or their carers can inject the medicine once they have been trained by a healthcare professional. For more information about using Praluent, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Praluent work?

The active substance in Praluent, alirocumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a specific enzyme called PCSK9. This enzyme attaches to cholesterol receptors on the surface of liver cells and causes these receptors to be absorbed and broken down inside the cells. These receptors control blood levels of cholesterol, especially LDL-cholesterol, by removing it from the bloodstream. By attaching and blocking PCSK9, Praluent prevents the receptors from being broken down inside cells and therefore increases the number of these receptors on the cell surface, where they can attach to LDL-cholesterol and remove it from the bloodstream. This helps to reduce the amount of LDL-cholesterol in the blood. Alirocumab also helps to reduce other fatty substances from blood in patients with mixed dyslipidaemia.

What benefits of Praluent have been shown in studies?

Hypercholesterolaemia and mixed dyslipidaemia

Praluent has been studied in 10 main studies involving over 5,000 adult patients with hypercholesterolaemia (including patients with heterozygous familial disease) and mixed dyslipidaemia. Some studies looked at Praluent taken on its own, while others studied Praluent in combination with other fat-lowering medicines, including patients on the maximum recommended doses of statins. Some studies compared Praluent with placebo (a dummy treatment) and others to another medicine for hypercholesterolaemia (ezetimibe). These studies showed that when Praluent was given on top of a statin it led to a substantial reduction in blood levels of LDL-cholesterol (between 39 and 62% more than placebo) after 6 months of treatment. When given on top of standard treatment or on its own, Praluent produced a 24 to 36% greater reduction in blood levels of LDL-cholesterol than ezetimibe.

Atherosclerotic heart disease

In a study involving over 18,000 patients who had established heart disease, less than 10% of patients given Praluent had a cardiovascular event (meaning death, heart attack, stroke, chest pain due to problems with the blood flow to the heart leading to hospitalisation) during the study compared with over 11% of patients given placebo.

What are the risks associated with Praluent?

The most common side effects with Praluent (which may affect up to 1 in 10 people) are injection site reactions such as pain and redness, problems affecting the nose and throat such as colds, and itching. The most common side effects leading to treatment discontinuation were local injection site reactions. For the full list of side effects and restrictions, see the package leaflet.

Why is Praluent authorised in the EU?

The European Medicines Agency decided that Praluent's benefits are greater than its risks and it can be authorised for use in the EU. The Agency noted that across all studies in patients with primary hypercholesterolaemia and mixed dyslipidaemia, including patients on maximum recommended doses of statins or those intolerant to them, treatment with Praluent led to a significant reduction in LDL-cholesterol levels, which is a known risk factor for cardiovascular (affecting the heart and blood vessels) disease. Therefore, Praluent has been approved for use in patients who do not adequately respond to the maximum tolerated dose of statins or who cannot be given statins.

In patients with atherosclerotic heart disease, Praluent reduced the number of cardiovascular events, in particular heart attacks and strokes. With regard to safety, the Agency noted an acceptable safety profile.

What measures are being taken to ensure the safe and effective use of Praluent?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Praluent have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Praluent are continuously monitored. Side effects reported with Praluent are carefully evaluated and any necessary action taken to protect patients.

Other information about Praluent

Praluent received a marketing authorisation valid throughout the EU on 23 September 2015.

Further information on Praluent can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/praluent.

This overview was last updated in 07-2020.