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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 in children from 8 years of age with heterozygous familial hypercholesterolaemia (high levels of blood cholesterol with a genetic cause that is inherited from one parent).

It is also used to reduce the risk of heart problems and strokes in adults 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 with 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.

Praluent contains the active substance alirocumab.

How is Praluent used?

Praluent is given as an injection under the skin of the abdomen (belly), thigh or upper arm, using a pre-filled syringe or pre-filled pen. The medicine can only be obtained with a prescription.

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.

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 low-density

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lipoprotein (LDL)-cholesterol, by removing it from the bloodstream. By attaching and blocking PCSK9, Praluent prevents the receptors from being broken down 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 adults 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 studies with patients on the maximum recommended doses of statins. Some studies compared Praluent with a placebo (dummy treatment) and others with ezetimibe (another medicine for hypercholesterolaemia). These studies showed that when Praluent was given together with 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 with standard treatment or on its own, Praluent led to a 24 to 36% greater reduction in blood levels of LDL-cholesterol than ezetimibe.

Heterozygous familial hypercholesterolaemia

In a study involving 153 children and adolescents aged 8 to 17 years with heterozygous familial hypercholesterolaemia, children given a low dose of Praluent once every 2 weeks had a 34% decrease in their LDL-cholesterol levels after 24 weeks, compared with a 10% increase in children given placebo. Children given a high dose of Praluent once every 4 weeks had a 38% decrease in LDL-cholesterol levels, compared with a 4% decrease in children given placebo.

Atherosclerotic heart disease

In a study involving over 18,000 adults 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?

For the full list of side effects and restrictions with Praluent, see the package leaflet.

The most common side effects with Praluent (which may affect up to 1 in 10 people) include 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.

Why is Praluent authorised in the EU?

The European Medicines 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. Comparable results were seen in children with heterozygous familial hypercholesterolaemia. In adults with atherosclerotic heart disease, Praluent reduced the number of cardiovascular events, in particular heart attacks and strokes. With regard to safety, the Agency

concluded that Praluent has an acceptable safety profile. The Agency therefore decided that Praluent's benefits are greater than its risks and it can be authorised for use in the EU.

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.

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