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Pravafenix (*pravastin / fenofibrate*)

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

What is Pravafenix and what is it used for?

Pravafenix is used in adults at high risk of heart disease whose low-density-lipoprotein (LDL) cholesterol is already being controlled with pravastatin alone or another medicine from the statin family, but who still need to improve their high-density-lipoprotein (HDL) cholesterol levels and reduce their levels of triglycerides (another type of fat) in the blood. Pravafenix is used in addition to other measures such as diet, exercise and weight reduction.

Pravafenix contains the active substances pravastatin and fenofibrate.

How is Pravafenix used?

Pravafenix can only be obtained with a prescription. It is available as capsules to be taken by mouth once a day with food, during the evening meal. Before starting treatment with Pravafenix, the doctor should first investigate all possible causes of the patient's abnormal cholesterol and triglyceride blood levels and recommend a suitable diet.

The patient's blood should be monitored regularly to see how the medicine is working. The doctor should stop treatment if an adequate response does not occur within three months.

How does Pravafenix work?

The active substances in Pravafenix, pravastatin and fenofibrate, work in different ways and their actions have a complementary effect.

Pravastatin belongs to a group of medicines called statins. It reduces total blood cholesterol by blocking the action of the HMG-CoA reductase, an enzyme (protein) in the liver involved in the production of cholesterol. As the liver needs cholesterol to produce bile, the reduced blood cholesterol level causes the liver cells to produce receptors that draw LDL cholesterol from the blood, reducing its level even further.

Fenofibrate attaches to the peroxisome proliferator-activated receptor alpha (PPAR alpha), which is involved in breaking down fat from the diet, especially triglycerides. When the receptors are activated, the breakdown of fats is accelerated, and this helps clear the blood of cholesterol and triglycerides.

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What benefits of Pravafenix have been shown in studies?

Because pravastatin and fenofibrate have been used in clinical practice for a long time, the company presented information from the scientific literature. Additionally, a main study showed that Pravafenix is more effective than pravastatin alone in reducing blood levels of non-HDL cholesterol.

The main study involved 248 patients at high risk of heart disease who had abnormal levels of cholesterol and triglycerides in the blood. Patients were either treated with Pravafenix or pravastatin alone. After 12 weeks of treatment, non-HDL cholesterol was reduced by an average of around 14% in patients taking Pravafenix, compared with an average of around 6% in patients taking pravastatin alone.

An additional study confirmed the effectiveness of Pravafenix compared with other statin medicines given alone in patients treated by different doctors such as family doctors, cardiologists or endocrinologists.

What are the risks associated with Pravafenix?

For the complete list of side effects and restrictions with Pravafenix, see the package leaflet.

The most common side effects with Pravafenix (which may affect up to 1 in 10 people) include abdominal distension (bloating), abdominal (belly) pain, constipation, diarrhoea, dry mouth, dyspepsia (heartburn), eructation (belching), flatulence (gas), nausea (feeling sick), abdominal discomfort, vomiting and raised blood levels of liver enzymes.

Pravafenix must not be used in patients aged less than 18 years or in patients with severe liver problems, moderate to severe kidney problems, photo allergy or phototoxic reactions (allergic reaction or skin damage due to light exposure) during treatment with fibrates or ketoprofen medicines. It must also not be used in patients with gall bladder disease, chronic or acute pancreatitis (inflammation of the pancreas) or a history of myopathy (muscle disorders) or rhabdomyolysis (breakdown of muscle fibres) following treatment with a statin or fibrate medicine. It must not be taken by women who are pregnant or breastfeeding.

Why is Pravafenix authorised in the EU?

Data from the scientific literature and from two studies show that Pravafenix, which combines a statin and fenofibrate, is more effective than a statin alone to reduce LDL cholesterol in patients who have high levels of triglycerides and low levels of HDL cholesterol. Regarding safety, side effects with Pravafenix were considered acceptable for the patients in which it is used.

The European Medicines Agency therefore decided that Pravafenix'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 Pravafenix?

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

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

Other information about Pravafenix

Pravafenix received a marketing authorisation valid throughout EU on 14 April 2011.

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

This overview was last updated in 10-2024.