EMA/79515/2011
EMEA/H/C/001243

EPAR summary for the public

Pravafenix

pravastatin/fenofibrate

This is a summary of the European public assessment report (EPAR) for Pravafenix. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Pravafenix.

What is Pravafenix?

Pravafenix is a medicine that contains the active substances pravastatin and fenofibrate. It is available as green and olive capsules containing 40 mg pravastatin and 160 mg fenofibrate.

What is Pravafenix used for?

Pravafenix is used in adults at high risk of heart disease whose 'low-density-lipoprotein' (LDL or 'bad') cholesterol is already being controlled with pravastatin alone but who still need to improve their cholesterol levels and to reduce their levels of triglycerides (a type of fat).

The medicine can only be obtained with a prescription.

How is Pravafenix used?

Before starting treatment with Pravafenix, the doctor should first investigate all possible causes of the patient's abnormal cholesterol and triglycerides levels and place the patient on a suitable diet.

The recommended dose is one capsule a day taken during the evening meal. The medicine should always be taken with food as it is less well absorbed from an empty stomach. The patient's blood should be monitored regularly to see how the medicine is working. The doctor should stop treatment if an adequate response is not seen within three months.

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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 the group called 'statins'. It reduces total blood cholesterol by blocking the action of HMG-CoA reductase, an enzyme 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 cholesterol from the blood, reducing its level even further. The cholesterol drawn out of the blood in this way is the LDL, or 'bad' cholesterol.

Fenofibrate is a 'PPAR agonist'. It activates a type of receptor called the 'peroxisome proliferator-activated receptor 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.

How has Pravafenix been studied?

Because pravastatin and fenofibrate have been used in medicines for a number of years, the company presented information from the scientific literature in addition to results from its own studies.

The company carried out one main study, in which Pravafenix was compared with pravastatin alone in 248 patients at high risk of heart disease who had abnormal levels of cholesterol and triglyceride fats. The main measure of effectiveness was the reduction in the level of cholesterol after 12 weeks (excluding HDL or 'good' cholesterol).

What benefit has Pravafenix shown during the studies?

In the main study Pravafenix was shown to be more effective than pravastatin alone in reducing non-HDL-cholesterol levels. Non-HDL-cholesterol levels were reduced on average by around 14% in patients taking Pravafenix compared with 6% in patients taking pravastatin alone.

What is the risk associated with Pravafenix?

The most common side effects with Pravafenix (seen in between 1 and 10 patients in 100) are abdominal distension (bloating), abdominal pain (stomach ache), constipation, diarrhoea, dry mouth, dyspepsia (heartburn), eructation (belching), flatulence (gas), nausea (feeling sick), abdominal discomfort, vomiting and raised blood levels of liver enzymes. For the full list of all side effects reported with Pravafenix, see the package leaflet.

Pravafenix should not be used in people who may be hypersensitive (allergic) to the active substances or any of the other ingredients. Pravafenix must not be used in patients aged below 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. 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 a fibrate. It must not be given to women who are pregnant or breastfeeding.

Why has Pravafenix been approved?

The CHMP looked at newly published data on the benefits of the combination of statins and fenofibrate. The Committee also noted that the benefits of Pravafenix were mainly in patients who had high levels

of triglyceride fats and low levels of HDL cholesterol. The Committee therefore decided that Pravafenix's benefits are greater than its risks in this group of patients and recommended that it be given marketing authorisation.

Other information about Pravafenix

The European Commission granted a marketing authorisation valid throughout the European Union for Pravafenix to Laboratoires SMB s.a. on 14 April 2011. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Pravafenix can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Pravafenix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2011.