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EPAR summary for the public

Cholestagel

colesevelam

This document is a summary of the European Public Assessment Report (EPAR) for Cholestagel. 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 Cholestagel.

What is Cholestagel?

Cholestagel is a medicine that contains the active substance colesevelam. It is available as white tablets (625 mg).

What is Cholestagel used for?

Cholestagel is used to lower cholesterol levels in adults with primary hypercholesterolaemia (high blood cholesterol levels). 'Primary' means that there is no disease causing the high cholesterol levels. Cholestagel is used in the following ways:

- as an add-on to a statin (another cholesterol-lowering medicine) and a cholesterol-lowering diet, to further reduce 'low-density-lipoprotein' (LDL or 'bad') cholesterol levels in patients who are not adequately controlled with a statin alone;
- as an add-on to a cholesterol-lowering diet, to reduce total-cholesterol and LDL-cholesterol levels in patients who cannot take statins;
- together with ezetimibe (another cholesterol-lowering medicine), with or without a statin. This combination can also be used in patients who have familial hypercholesterolaemia (primary hypercholesterolaemia that runs in the family).

The medicine can only be obtained with a prescription.

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How is Cholestagel used?

The recommended dose of Cholestagel is six tablets a day when it is taken on its own, and four to six tablets a day when it is taken in combination with other medicines. The tablets need to be taken with food and drink. They can either be taken all at once, or split into two doses during the day. The maximum dose is seven tablets a day when it is taken on its own, and six tablets a day when it is taken with other medicines.

Patients should start a cholesterol-lowering diet before treatment and continue it throughout treatment. Blood cholesterol levels should also be measured before and during treatment to check the patient's response.

How does Cholestagel work?

The active substance in Cholestagel, colesevelam, is not absorbed by the body, but stays in the gut, where it attaches to substances called bile acids and carries them out of the body in the faeces. Because the bile acids are prevented from being absorbed into the bloodstream, the liver is forced to make more bile acids. As the liver uses cholesterol to make bile acids, this reduces cholesterol levels in the blood. Lowering cholesterol, especially LDL cholesterol, can reduce the risk of heart disease.

How has Cholestagel been studied?

Cholestagel has been compared with placebo (a dummy treatment) in seven main studies involving adults with primary hypercholesterolaemia. Three of these studies looked at Cholestagel taken in combination with a statin (lovastatin, simvastatin or atorvastatin) in 491 patients, two looked at Cholestagel taken on its own in 592 patients, and one looked at Cholestagel in combination with ezetimibe in 86 patients. The final study looked at Cholestagel as an add-on to ezetimibe and a statin in 86 adults with familial hypercholesterolaemia. The main measure of effectiveness was the decrease in LDL-cholesterol levels after four to six weeks, except for one of the studies looking at Cholestagel taken on its own, which measured the cholesterol levels after six months.

What benefit has Cholestagel shown during the studies?

Looking at the results of the three studies in which Cholestagel was used with a statin, there was an 8% reduction in LDL-cholesterol levels with 2.3 g Cholestagel (about four tablets) after six weeks, as compared to placebo. There was a 16% reduction with 3.8 g Cholestagel (about six tablets).

In the studies looking at Cholestagel taken on its own, more than half of the patients receiving 3.8 or 4.5 g Cholestagel (about six to seven tablets) had a decrease in LDL-cholesterol level of 15 to 18% after six weeks. In the longer study, the decrease seen at six weeks with 3.8 g Cholestagel (about six tablets) was maintained for six months. In comparison, the patients taking placebo had no changes in LDL-cholesterol levels. Cholestagel was equally effective when it was taken in the morning, in the evening, or twice a day.

The combination of Cholestagel and ezetimibe was more effective than ezetimibe taken with placebo: there was a fall of 32% in LDL-cholesterol levels in the patients taking Cholestagel and a fall of 21% in those taking placebo. When added to ezetimibe and a statin, Cholestagel caused a reduction of 11% in LDL-cholesterol levels after six weeks in patients with familial hypercholesterolaemia, compared with a rise of 7% when adding placebo.

What is the risk associated with Cholestagel?

In studies, the most common side effects with Cholestagel (seen in more than 1 patient in 10) were flatulence (gas) and constipation. For the full list of all side effects reported with Cholestagel, see the Package Leaflet.

Cholestagel should not be used in people who may be hypersensitive (allergic) to colesevelam or any of the other ingredients. It must not be used in patients whose gut or bile duct is blocked.

Why has Cholestagel been approved?

The CHMP concluded that Cholestagel's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Cholestagel:

The European Commission granted a marketing authorisation valid throughout the European Union for Cholestagel to Genzyme Europe B.V. on 10 March 2004. The marketing authorisation is valid for an unlimited period.

The full EPAR for Cholestagel can be found here. For more information about treatment with Cholestagel, read the Package Leaflet (also part of the EPAR).

This summary was last updated in 04-2010.