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**EPAR summary for the public**

# Cholib

fenofibrate / simvastatin

This is a summary of the European public assessment report (EPAR) for Cholib. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Cholib.

For practical information about using Cholib, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Cholib and what is it used for?

Cholib is a medicine for improving blood fat levels. It contains two active substances, fenofibrate and simvastatin, and is used together with a low fat diet and exercise with the aim of reducing patients' levels of triglycerides (a type of fat) and increasing their levels of 'good' cholesterol (HDL cholesterol). Cholib is to be used in adults at high risk of heart disease whose levels of 'bad' cholesterol (LDL cholesterol) are already being controlled with the corresponding dose of simvastatin alone.

## How is Cholib used?

Before starting treatment with Cholib, possible causes of the abnormal levels of blood fats should be adequately treated and patients should be placed on a standard fat-lowering diet.

Cholib can only be obtained with a prescription and is available as tablets (145/20 mg and 145/40 mg). The recommended dose is one tablet a day to be swallowed whole with a glass of water. Grapefruit juice should be avoided during Cholib treatment as this is known to alter the amount of simvastatin in the blood.

## How does Cholib work?

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

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Fenofibrate is a 'PPARα agonist'. This means that it activates a type of receptor called the 'peroxisome proliferator-activated receptor alpha' (PPARα), which is involved in breaking down fats from diet, especially triglycerides. When these receptors are activated, the breakdown of fats speeds up, which helps clear the blood of 'bad' cholesterol and triglycerides.

The second active substance, simvastatin, 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 'bad' cholesterol.

## What benefits of Cholib have been shown in studies?

Cholib has been shown to be more effective than statins alone in reducing levels of triglycerides and increasing levels of good cholesterol.

In a main study comparing Cholib 145/20 mg with simvastatin 40 mg in 1,050 patients not adequately treated with 20 mg simvastatin alone, triglyceride levels decreased by around 36% with Cholib after 12 weeks compared with 12% with simvastatin. In addition, levels of good cholesterol increased by around 7% with Cholib compared with around 2% with simvastatin.

Another study compared Cholib 145/40 mg with simvastatin 40 mg in 450 patients not adequately treated with 40 mg simvastatin alone. It showed that Cholib led to a greater reduction in triglyceride levels (33% versus 7%) and to higher levels of good cholesterol (6% increase versus a 1% decrease).

Two further studies compared Cholib with other statins (atorvastatin and pravastatin) and showed Cholib to be more effective than those statins given alone.

## What are the risks associated with Cholib?

The most common side effects with Cholib are raised blood creatinine levels, upper respiratory tract infection (colds), increased blood platelet counts, gastroenteritis (diarrhoea and vomiting) and increased levels of alanine aminotransferase (a liver enzyme). For the full list of all side effects reported with Cholib, see the package leaflet.

Cholib must not be used in people who are hypersensitive (allergic) to peanuts, soya lecithin or any of the ingredients of the medicine. It must also not be used in pregnant or breast-feeding women, in people known to have light-induced reactions to fibrates or ketoprofen, or those who have liver or gallbladder disease, pancreatitis, or moderately or severely reduced kidney function, or who have previously had muscle problems while taking statins or fibrates. For the full list of restrictions, see the package leaflet.

## Why is Cholib approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) considered that the combination of fenofibrate and simvastatin has been shown to be effective at improving blood fat levels. In all studies the reductions in triglycerides and the increases in good cholesterol were higher with Cholib than with a statin alone. The Committee also noted that the combination of fenofibrate and simvastatin is already being used in clinical practice.

With regard to the safety of Cholib, the side effects reported in the studies were consistent with what is known about the two active substances and there were no major concerns. The Committee therefore

concluded that Cholib's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Cholib is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Cholib, including the appropriate precautions to be followed by healthcare professionals and patients.

## Other information about Cholib

The European Commission granted a marketing authorisation valid throughout the European Union for Cholib on 26 August 2013.

The full EPAR for Cholib 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 Cholib, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2013.