



27 June 2013
EMA/380955/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Cholib

fenofibrate/simvastatin

On 27 June, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cholib 145mg/40mg and 145mg/20mg, film-coated tablets, intended to be indicated as adjunctive therapy to diet and exercise in high cardiovascular risk adult patients with mixed dyslipidaemia to reduce triglycerides and increase HDL cholesterol levels when LDL cholesterol levels are adequately controlled with the corresponding dose of simvastatin monotherapy 20 mg or 40 mg. The applicant for this medicinal product is Abbott Healthcare Products Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substances of Cholib are fenofibrate/simvastatin; Cholib being a combination of two lipid modifying substances (HMG-CoA reductase inhibitors in combination with other lipid modifying substances, ATC code C10BA04). Fenofibrate, a Peroxisome Proliferator-Activated Receptor (PPAR) α agonist, reduces both, low-density lipoprotein (LDL) and very low density lipoprotein (VLDL) levels, increases high-density lipoprotein (HDL) levels and reduces triglycerides levels. Simvastatin is an inhibitor of 3-Hydroxy-3-MethylGlutaryl-Coenzyme A (HMG-CoA) reductase and has been shown to reduce both normal and elevated LDL cholesterol concentrations.

The benefits with Cholib are the complementary lipid-modifying respective effects of simvastatin and fenofibrate. The most common side effects are upper respiratory tract infection, gastroenteritis, increased platelet count and increased alanine aminotransferase and blood creatinine.

A pharmacovigilance plan for Cholib will be implemented as part of the marketing authorisation.

The approved indication is:

"Cholib is indicated as adjunctive therapy to diet and exercise in high cardiovascular risk adult patients with mixed dyslipidaemia to reduce triglycerides and increase HDL C levels when LDL C levels are adequately controlled with the corresponding dose of simvastatin monotherapy."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Cholib and therefore recommends the granting of the marketing authorisation.