18 February 2010
EMA/CHMP/103005/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Cholestagel

(colesevelam)

On 18 February 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Cholestagel. The marketing authorisation holder for this medicinal product is Genzyme Europe B.V. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:
"Cholestagel can also be used in combination with ezetimibe, with or without a statin, in adult patients with primary hypercholesterolaemia, including patients with familial hypercholesterolaemia (see section 5.1)."

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Cholestagel will be as follows[2]:

"*Cholestagel co administered with a 3 hydroxy 3 methyl glutaryl coenzyme A (HMG CoA) reductase inhibitor (statin) is indicated as adjunctive therapy to diet to provide an additive reduction in low density lipoprotein cholesterol (LDL C) levels in adult patients with primary hypercholesterolaemia who are not adequately controlled with a statin alone.*

Cholestagel as monotherapy is indicated as adjunctive therapy to diet for reduction of elevated total cholesterol and LDL C in adult patients with isolated primary hypercholesterolaemia, in whom a statin is considered inappropriate or is not well tolerated.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

[2] The text in bold represents the new or the amended indication.

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Cholestagel can also be used in combination with ezetimibe, with or without a statin, in adult patients with primary hypercholesterolaemia, including patients with familial hypercholesterolaemia (see section 5.1).”