



18 May 2017
EMA/CHMP/310511/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Sevelamer carbonate Zentiva

sevelamer carbonate

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Sevelamer carbonate Zentiva. The marketing authorisation holder for this medicinal product is Genzyme Europe BV.

The CHMP adopted a new indication as follows:

“Sevelamer carbonate Zentiva is indicated for the control of hyperphosphataemia in paediatric patients (>6 years of age and a body surface area (BSA) of >0.75 m²) with chronic kidney disease.”

For information, the full indications for Sevelamer carbonate Zentiva will be as follows:²

“Sevelamer carbonate Zentiva is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.

Sevelamer carbonate Zentiva is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus > 1.78 mmol/L.

Sevelamer carbonate Zentiva is indicated for the control of hyperphosphataemia in paediatric patients (>6 years of age and a body surface area (BSA) of >0.75 m²) with chronic kidney disease.

Sevelamer carbonate Zentiva should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D₃ or one of its analogues to control the development of renal bone disease.”

Detailed recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.

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

² New text in bold

