20 November 2014
EMA/CHMP/703681/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sevelamer carbonate Zentiva

sevelamer

On 20 November 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sevelamer carbonate Zentiva, strengths 800 mg and 2.4g, film-coated tablet and powder for oral suspension, intended for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis and is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus $\geq$ 1.78 mmol/L. Sevelamer carbonate Zentiva should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.

The applicant for this medicinal product is Genzyme Europe BV. 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 substance of Sevelamer carbonate Zentiva is sevelamer, a phosphate binder (ATC Code: V03AE02). It contains multiple amines separated by one carbon from the polymer backbone. These amines become partially protonated in the intestine and interact with phosphate ions through ionic and hydrogen bonding. By binding phosphate in the gastrointestinal tract, sevelamer lowers the phosphate concentration in the serum. Sevelamer carbonate Zentiva decreases the incidence of hypercalcaemic episodes as compared to patients using calcium based phosphate binders alone, probably because the product itself does not contain calcium.

The benefits with Sevelamer carbonate Zentiva are its phosphate-lowering effect for controlling hyperphosphataemia in adult patients on dialysis and in adult patients with chronic kidney disease not on dialysis with serum phosphorus $\geq$ 1.78 mmol/l. The most common side effects are nausea, vomiting, upper abdominal pain, constipation (very common) and diarrhoea, dyspepsia, flatulence, abdominal pain (common).

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

A pharmacovigilance plan for Sevelamer carbonate Zentiva will be implemented as part of the marketing authorisation.

The approved indication is:

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 $\geq$ 1.78 mmol/L.

Sevelamer carbonate Zentiva should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D_3 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 summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and 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 Sevelamer carbonate Zentiva and therefore recommends the granting of the marketing authorisation.