EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 December 2014
EMA/CHMP/761518/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tasermity

sevelamer hydrochloride

On 18 December 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 Tasermity, 800 mg, oral use, intended for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Sevelamer hydrochloride should be used within the context of a multiple therapeutic approach, which could include calcium supplements, 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 Tasermity is sevelamer hydrochloride, 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.

The benefits with Tasermity are its phosphate-lowering effect for controlling hyperphosphataemia in adult patients on dialysis. The most common side effects are nausea and vomiting.

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

The approved indication is:

Tasermity is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Sevelamer hydrochloride should be used within the context of a multiple therapeutic approach, which could include calcium supplements, 1,25-dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.

[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.

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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 Tasermity and therefore recommends the granting of the marketing authorisation.