21 July 2011
EMA/CHMP/555635/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Matever
levetiracetam

On 21 July 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Matever 250 mg, 500 mg, 750 mg and 1000 mg film-coated tablets and 100 mg/ml concentrate for solution for infusion intended for the treatment of epilepsy. The applicant for this medicinal product is Pharmathen S.A. 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 Matever is levetiracetam, an antiepileptic agent (ATC code: N03AX14). Levetiracetam is a pyrrolidone derivative chemically unrelated to existing antiepileptic active substances. The mechanism of action of levetiracetam still remains to be fully elucidated but appears to be different from the mechanisms of current antiepileptic medicinal products. In *vitro* and in *vivo* experiments suggest that levetiracetam does not alter basic cell characteristics and normal neurotransmission.

Matever is a generic of Keppra, which has been authorised in the EU since 29 September 2000. Studies have demonstrated the satisfactory quality of Matever and its bioequivalence with Keppra. A question-and-answer document on generic medicines can be found here.

The approved indication is as follows:

“Monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy.

Levetiracetam is indicated as adjunctive therapy:

- in the treatment of partial onset seizures with or without secondary generalisation in adults, children and infants from 1 month of age with epilepsy.
- in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy.

[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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- in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy."

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

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