21 July 2011
EMA/CHMP/508445/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Levetiracetam Actavis

levetiracetam/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 Levetiracetam Actavis, 250 mg, 500 mg, 750 mg and 1000 mg, film-coated tablets intended for the treatment of epilepsy. The applicant for this medicinal product is Actavis Group PTC ehf. 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 Levetiracetam Actavis is levetiracetam, an antiepileptic (N03AX14). Levetiracetam is a pyrrolidone derivative chemically unrelated to existing antiepileptic active substances. The exact mechanism by which levetiracetam acts to treat epilepsy is unknown, however, the drug binds to a synaptic vesicle protein, SV2A which is believed to impede nerve conduction across synapses.

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

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

The approved indication is: “Levetiracetam Actavis is indicated as 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 Actavis 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.

[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 myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy.
- 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 quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Levetiracetam Actavis and therefore recommends the granting of the marketing authorisation.