EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
EMA/443446/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Levetiracetam Hospira

levetiracetam

On 24 October 2013 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 Hospira 100 mg/ml concentrate for solution for infusion intended for the treatment of epilepsy. The applicant for this medicinal product is Hospira UK Limited. 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 Hospira 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 it appears to interfere with a protein called synaptic vesicle protein 2A, which is found in the spaces between nerves and is involved in the release of chemical messengers from nerve cells. This helps levetiracteam to stabilise electrical activity in the brain and prevent seizures.

Levetiracetam Hospira is a generic of Keppra, which has been authorised in the EU since 29 September 2000. Studies have demonstrated the satisfactory quality of Levetiracetam Hospira. Levetiracetam Hospira is administered intravenously and is 100% bioavailable. Therefore, a bioequivalence study versus the reference product Keppra was not required. A question and answer document on generic medicines can be found here.

The approved indication is as follows:

Levetiracetam Hospira is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed 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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Levetiracetam Hospira is indicated as adjunctive therapy

- in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy.
- 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.

Levetiracetam Hospira concentrate is an alternative for patients when oral administration is temporarily not feasible.

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 the data submitted, considers there to be a favourable benefit to risk balance for Levetiracetam Hospira and therefore recommends the granting of the marketing authorisation.