European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 September 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
RIVASTIGMINE HEXAL

International Non-proprietary Name (INN): ***rivastigmine***

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion**, recommending the granting of a marketing authorisation for the medicinal product Rivastigmine Hexal 1.5 mg, 3 mg, 4.5 mg, 6 mg hard capsules and 2 mg / ml. oral solution intended for the symptomatic treatment of mild to moderately severe Alzheimer's dementia and of mild to moderately severe dementia in patients with idiopathic Parkinson's disease.
The applicant for this medicinal product is Hexal AG.

The active substance of Rivastigmine Hexal is rivastigmine an anticholinesterases medicinal product *(*N06DA03*)*.
Rivastigmine Hexal is the same as Exelon, which is already authorised in the European Union. The company that holds Exelon has agreed that its scientific data on Exelon can be used to assess Rivastigmine Hexal.

The approved indication is: "Rivastigmine is indicated for the symptomatic treatment of of mild to moderately severe Alzheimer's dementia and mild to moderately severe dementia in patients with idiopathic Parkinson's disease."

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 that there is a favourable benefit risk balance for Rivastigmine Hexal, and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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