14 April 2011
EMA/CHMP/98238/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Rivastigmine Actavis

Rivastigmine

On 14 April 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 Actavis 1.5 mg, 3 mg, 4.5 mg, 6 mg hard capsules 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 Actavis Group PTC ehf

The active substance of Rivastigmine Actavis is Rivastigmine, an anticholinesterases medicinal product (N06DA03). Rivastigmine is an acetyl- and butyrylcholinesterase inhibitor of the carbamate type, thought to facilitate cholinergic neurotransmission by slowing the degradation of acetylcholine released by functionally intact cholinergic neurones. Thus, Rivastigmine may have an ameliorative effect on cholinergic-mediated cognitive deficits in dementia associated with Alzheimer's disease and Parkinson's disease.

Rivastigmine Actavis is a generic of Exelon, which has been authorised in the EU since 12 May 1998. Studies have demonstrated the satisfactory quality of Rivastigmine Actavis, and its bioequivalence with Exelon. A question and answer document on generic medicines can be found here.

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 (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.

[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.
** 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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The CHMP, on the basis of the data submitted, considers that there is a favourable benefit risk balance for Rivastigmine Actavis, and therefore recommends the granting of the marketing authorisation.