21 February 2013
EMA/CHMP/82387/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Nemdatine

Memantine

On 21 February 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 Nemdatine, 5 mg, 10 mg, 15 mg and 20 mg, film-coated tablets intended for the treatment of patients with moderate to severe Alzheimer's disease. 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 Nemdatine is memantine hydrochloride, a psychoanaleptic, anti-dementia drug (N06DX01). Memantine is a voltage-dependent, moderate-affinity non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist, modulating the effects of pathologically elevated tonic levels of glutamate that may lead to neuronal dysfunction.

Nemdatine is a generic of Ebixa, which has been authorised in the EU since 15-05-2002. Studies have demonstrated the satisfactory quality of Nemdatine *and its bioequivalence with the reference product* Ebixa. A question and answer document on generic medicines can be found here.

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

The approved indication is: "Treatment of patients with moderate to severe Alzheimer's disease". It is proposed that treatment with Nemdatine should be initiated and supervised by a physician experienced in the diagnosis and treatment of Alzheimer's dementia.

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.

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