



21 February 2013
EMA/CHMP/82409/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (initial authorisation)

Memantine LEK

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 Memantine LEK, 10 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 Pharmathen S.A. 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 Memantine LEK 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.

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

A pharmacovigilance plan for Memantine LEK 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 Memantine LEK 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.



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

Medicinal product no longer authorised