19 September 2013
EMA/CHMP/428241/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Memantine Accord

memantine

On 19 September 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 Accord 5 mg, 10 mg, 15 mg and 20 mg, film-coated tablets intended for treatment of patients with moderate to severe Alzheimer's disease. The applicant for this medicinal product is Accord Healthcare 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 Memantine Accord 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 Accord is a generic of Axura, which has been authorised in the EU since 15 May 2002. Studies have demonstrated the satisfactory quality of Memantine Accord, a bioequivalence study with the reference product Axura was not required. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Memantine Accord 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 Memantine Accord is prescribed by physicians experienced in the 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 Memantine Accord and therefore recommends the granting of the marketing authorisation.