20 September 2012
EMA/CHMP/589593/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Memantine Merz

memantine

On 20 September 2012, 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 Merz 10mg, 20mg, 5 mg + 10 mg + 15 mg + 20 mg film coated tablets and 5mg/pump actuation oral solution intended for the treatment of moderate to severe Alzheimer's disease. The applicant for this medicinal product is Merz Pharmaceuticals GmbH. 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 Merz is memantine hydrochloride, an anti-dementia drug (ATC Code N06DX01) which is a non-competitive NMDA receptor antagonist. The excessive release of glutamate is claimed to be associated with neurodegeneration in acute and chronic disorders such as hypoxia, ischaemia, stroke and perhaps Alzheimer's disease.

The benefits with Memantine Merz are its ability to show a statistically significant effect in preventing worsening in cognitive, global and functional domains in comparison to placebo. The most common side effects are dizziness, headache, constipation, somnolence and hypertension.

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

The approved indication is: Treatment of patients with moderately severe to severe Alzheimer's disease. It is proposed that treatment 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 made 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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