EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

FGK Representative Service GmbH withdraws its marketing authorisation application for Memantine FGK (memantine)

The European Medicines Agency has been formally notified by FGK Representative Service GmbH of its decision to withdraw its application for centralised marketing authorisation for the medicine Memantine FGK (memantine), 7 mg, 14 mg, 21 mg and 28 mg, prolonged-release hard capsule. It was intended to be used for the treatment of patients with moderate to severe Alzheimer's disease.

The application for the marketing authorisation for Memantine FGK was submitted to the Agency on 31 May 2012. It was submitted as a hybrid application of Axura. At the time of the withdrawal, the medicine was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that it is withdrawing the application for strategic reasons.

More information about Memantine FGK and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the CHMP meeting of 14-17 January 2013.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. Applications for so-called hybrid medicines rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data. More details about hybrid applications can be found on page 7 of the document: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004018.pdf

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4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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