



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public statement

Memantine LEK (memantine hydrochloride)

Withdrawal of the marketing authorisation in the European Union

On 6 September 2024, the European Commission withdrew the marketing authorisation for Memantine LEK (memantine hydrochloride) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Pharmathen S.A., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Memantine LEK was granted marketing authorisation in the EU on 22 April 2013 for the treatment of Alzheimer's disease. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2018.

Memantine LEK is a generic medicine of Ebixa. There are other generic medicinal products of Ebixa authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Memantine LEK will be updated to indicate that the marketing authorisation is no longer valid.

