01 October 2015
EMEA/H/C/000227

Public statement

Sonata

Withdrawal of the marketing authorisation in the European Union

On 3 July 2015, the European Commission withdrew the marketing authorisation for Sonata (zaleplon) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Meda AB, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Sonata was granted marketing authorisation in the EU on 12 March 1999 for treatment of insomnia. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2004.

The European Public Assessment Report (EPAR) for Sonata will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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