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Press Office

Public statement

Zerene (zaleplon)

Withdrawal of the marketing authorisation in the European Union

On 21 April 2009, the European Commission issued a marketing authorisation valid throughout the European Union (EU) for the medicinal product Zerene (zaleplon), indicated for the treatment of patients with insomnia who have difficulty falling asleep, only when the disorder is severe, disabling or subjecting the individual to extreme distress.

The Marketing Authorisation Holder (MAH) responsible for Zerene was Meda AB. The European Commission was notified by a letter dated 24 April 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation for Zerene, as of the Commission Decision date on the withdrawal, for commercial reasons.

Therapeutic alternatives are available throughout the European Union. Zerene was a duplicate application to Sonata, which is marketed in several EU countries. The MAH will maintain the Marketing Authorisations for Sonata. Patients taking Zerene are advised to consult their physician.

On 23 August 2012 the European Commission issued a decision to withdraw the marketing authorisation for Zerene.

Pursuant to this decision the European Public Assessment Report for Zerene will be updated to reflect that the marketing authorisation is no longer valid.

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