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Public statement

Nuedexta

Withdrawal of the marketing authorisation in the European Union

On 15 February 2016 the European Commission withdrew the marketing authorisation for Nuedexta (dextromethorphan / quinidine) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Jenson Pharmaceutical Services Ltd, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Nuedexta was granted marketing authorisation in the EU on 24 June 2013 for treatment of pseudobulbar affect (PBA) in adults. The product had not been marketed in the EU.

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Report (EPAR) for Nuedexta will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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