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Public statement

Numient

Withdrawal of the marketing authorisation in the European Union

On 2 April 2019, the European Commission withdrew the marketing authorisation for Numient (levodopa / carbidopa) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Amneal Pharma Europe Limited, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Numient was granted marketing authorisation in the EU on 19 November 2015 for symptomatic treatment of adult patients with Parkinson's disease. The marketing authorisation was initially valid for a 5-year period. The product had not been marketed in the EU.

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European Public Assessment Report (EPAR) for Numient will be updated to indicate that the marketing authorisation is no longer valid.

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