



24 September 2015  
EMA/CHMP/519889/2015  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Numient

levodopa / carbidopa

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Numient, intended for the treatment of Parkinson's disease. The applicant for this medicinal product is Impax Laboratories Netherlands BV.

Numient will be available as 95 mg/23.75 mg, 145 mg/36.25 mg, 195 mg/48.75 mg and 245 mg/61.25 mg modified-release capsules. The active substances of Numient are levodopa and carbidopa (ATC code: N04BA02). Levodopa is a precursor of dopamine, and is given as dopamine replacement therapy in Parkinson's disease. Carbidopa is a peripheral aromatic amino acid decarboxylase inhibitor. It prevents metabolism of levodopa to dopamine in the peripheral circulation, ensuring that a higher proportion of the dose reaches the brain, where dopamine exerts its therapeutic effects.

The benefits with Numient are its ability to improve the motor symptoms of Parkinson's disease in patients with early or advanced form of the disease. The most common side effects are nausea (occurring in approximately 12% of patients), dizziness, headache, and dyskinesia (each occurring in approximately 8% of patients) and insomnia (occurring in approximately 6% of patients).

The full indication is: "Symptomatic treatment of adult patients with Parkinson's disease."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

