



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 July 2019  
EMA/CHMP/394791/2019  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Inbrija levodopa

On 25 July 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Inbrija, intended for the treatment of symptoms of off periods in Parkinson's disease. The applicant for this medicinal product is Acorda Therapeutics Ireland Limited.

Inbrija will be available as hard capsules containing inhalation powder (33 mg) to be used with an oral inhaler. The active substance of Inbrija is levodopa (ATC code: N04BA01) which is a precursor of dopamine, and is given as dopamine replacement therapy in Parkinson's disease.

The benefits with Inbrija are its ability to increase levodopa plasma concentrations and provide relief of off periods. The most common side effects are cough, falls, upper respiratory tract infections, new or increased dyskinesia and discoloured sputum.

The full indication is: "Inbrija is indicated for the intermittent treatment of episodic motor fluctuations (off episodes) in adult patients with Parkinson's disease (PD) treated with a levodopa/dopa-decarboxylase inhibitor."

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

