25 June 2026
EMADOC-1829012207-54127
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Hopledo

levodopa / carbidopa

On 25 June 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Hopledo, intended for the treatment of adults with Parkinson's disease and moderate to severe motor fluctuations.

The applicant for this medicinal product is Zambon S.p.A.

Hopledo will be available as 140 mg / 35 mg, 210 mg / 52.5 mg, 280 mg / 70 mg and 350 mg / 87.5 mg modified-release hard capsules. The active substances of Hopledo are levodopa and carbidopa, dopaminergic agents (ATC code: N04BA02). Hopledo modified-release hard capsules contain immediate-release granules and extended-release beads. The immediate-release granules consist of levodopa and carbidopa with a disintegrant polymer to allow for rapid dissolution. The extended-release beads consist of levodopa, coated with a sustained-release polymer to allow for slow release of the drug, a mucoadhesive polymer to keep the beads adhered to the area of absorprion longer and an enteric coating to prevent the beads from disintegrating too early in the stomach.

The benefits of Hopledo are its ability to increase levodopa plasma concentrations and provide relief from motor fluctuations (alternating changes in the ability to move) in adults with Parkinson's disease when these fluctuations are not sufficiently controlled with oral levodopa/dopa decarboxylase (DDC) inhibitor-based treatment regimens.

The most common side effects with Hopledo include dyskinesia, nausea, dry mouth and dizziness.

The full indication is:

> Treatment of adult patients with Parkinson’s disease and moderate to severe motor fluctuations who have not been sufficiently stabilised with oral levodopa/dopa decarboxylase (DDC) inhibitor based treatment regimens.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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languages after the marketing authorisation has been granted by the European Commission.