26 February 2026
EMA/CHMP/370118/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Onerji

levodopa / carbidopa

On 26 February 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 Onerji, intended for the treatment of adults with advanced Parkinson's disease.

The applicant for this medicinal product is Tanabe Pharma GmbH.

The active substances of Onerji are levodopa and carbidopa, anti-Parkinson drugs (ATC code: N04BA02). Onerji will be available as a 60 mg (levodopa) + 7.5 mg (carbidopa) per mL solution for infusion. Onerji is administered as a continuous subcutaneous infusion and should only be used with the Yurway Delivery System or the Crono Twin ND pump. Levodopa, the metabolic precursor of dopamine, crosses the blood-brain barrier and is converted into dopamine in the brain. This helps reduce the symptoms of Parkinson’s disease. The other active substance in Onerji, carbidopa, helps levodopa work better by stopping it from being broken down too early in the body, so more of it reaches the brain. This also reduces side effects allowing levodopa to be used more effectively.

The benefits of Onerji are its ability to increase levodopa plasma concentrations and provide relief of motor fluctuations (alternating changes in the ability to move) in adults with advanced Parkinson's disease when these fluctuations are not sufficiently controlled by oral anti-Parkinson medicinal products.

The most common side effects are infusion site reactions (including nodule, haematoma, pain, infection, erythema and eschar) and dyskinesia.

The full indication is:

> Onerji is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease which are not sufficiently controlled by oral anti-Parkinson medicinal products.

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

[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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