28 April 2016
EMA/CHMP/268284/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ongentys

opicapone

On 28 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ongentys, indicated as adjunctive therapy in adult patients with Parkinson's disease and motor fluctuations. The applicant for this medicinal product is Bial-Portela & Cª, S.A.

Ongentys will be available as hard capsules (25 mg and 50 mg). The active substance of Ongentys is opicapone, a peripheral, selective and reversible COMT inhibitor (ATC code: N04) that increases L-DOPA plasma levels when used concomitantly with L-DOPA/DOPA-decarboxylase inhibitors (DDCIs).

The benefits with Ongentys are its ability to decrease off-time (time when patients are severely restricted by their symptoms) and to increase on-time without troublesome dyskinesia. The most common side effects are dyskinesia, constipation, insomnia, dry mouth and dizziness.

The full indication is:

"Ongentys is indicated as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations."

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.

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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