16 December 2021
EMA/CHMP/679312/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ontilyv

opicapone

On 16 December 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ontilyv, intended for the treatment of Parkinson's disease

The applicant for this medicinal product is Bial Portela & Companhia S.A.

Ontilyv will be available as hard capsules (25 mg and 50 mg). The active substance of Ontilyv is opicapone, a peripheral, selective and reversible COMT inhibitor (ATC code: N04BX04) that increases L-DOPA plasma levels when used concomitantly with L-DOPA/DOPA-decarboxylase inhibitors (DDCIs).

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

The application for Ontilyv was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Ontilyv is Ongentys.

The full indication is:

Ontilyv is indicated as adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) 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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