18 December 2014
EMA/CHMP/741610/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xadago

safinamide

On 18 December 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xadago, 50 mg and 100 mg, film-coated tablet intended for the treatment of Parkinson's disease. The applicant for this medicinal product is Zambon SpA. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Xadago is safinamide, a highly selective and reversible MAO-B inhibitor causing an increase in extracellular levels of dopamine in the striatum. Xadago is also associated with state-dependent inhibition of voltage-gated sodium (Na^+) channels, and modulation of stimulated release of glutamate.

The benefits with Xadago are its ability to improve the ON time in patients with motor fluctuations, currently receiving L-dopa alone or in combination with other PD medications. The most common side effects are dyskinesia, somnolence, dizziness, headache, insomnia, nausea and orthostatic hypotension.

A pharmacovigilance plan for Xadago will be implemented as part of the marketing authorisation.

The approved indication is: "Xadago is indicated for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients."

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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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Xadago and therefore recommends the granting of the marketing authorisation.