20 November 2014
EMA/CHMP/693590/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rasagiline ratiopharm

rasagiline

On 20 November 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 Rasagiline ratiopharm, 1 mg, tablet indicated for the treatment of idiopathic Parkinson's disease (PD) as monotherapy (without levodopa) or as adjunct therapy (with levodopa) in patients with end of dose fluctuations. The applicant for this medicinal product is Teva B.V. 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 Rasagiline ratiopharm is rasagiline.

The benefits with Rasagiline ratiopharm are to reduce symptoms of Parkinson's disease as monotherapy in early patients and to reduce "OFF time" as adjunct therapy (with levodopa) in patients with end of dose fluctuations. The most common side effects are headache in monotherapy and abnormal movements (dyskinesia) in adjunct therapy.

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

The approved indication is: "Treatment of idiopathic Parkinson's disease (PD) as monotherapy (without levodopa) or as adjunct therapy (with levodopa) in patients with end of dose fluctuations".

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.

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

[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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