23 June 2011
EMA/CHMP/456583/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Entacapone Orion

entacapone

On 23 June 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the granting of a marketing authorisation for the medicinal product Entacapone Orion 200 mg film-coated tablets intended for the treatment of Parkinson's disease. The applicant for this medicinal product is Orion Corporation. 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 Entacapone Orion is entacapone, ATC code N04BX02. Entacapone is a reversible, specific and mainly peripherally acting catechol-O-methyl transferase (COMT) inhibitor which is designed for concomitant administration with levodopa preparations.

The benefits with Entacapone Orion are its ability to decrease the metabolic loss of levodopa to 3-O-methyldopa by inhibiting the COMT enzyme. The amount of levodopa available to the brain is increased, and entacapone thus prolongs the clinical response to levodopa.

The most common side effects are gastrointestinal symptoms which include nausea, vomiting, abdominal pain, constipation and diarrhoea, and side effects related to increased dopaminergic activity like dyskinesia and hyperkinesia.

The approved indication is: "Entacapone is indicated as an adjunct to standard preparations of levodopa/benserazide or levodopa/carbidopa for use 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 will be 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 Entacapone Orion and therefore recommends the granting of the marketing authorisation.