23 June 2011
EMA/CHMP/456787/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Levodopa/Carbidopa/Entacapone Orion

levodopa/carbidopa/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 Levodopa/Carbidopa/Entacapone Orion, 50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg, 150/37.5/200 mg and 200/50/200 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 substances of Levodopa/Carbidopa/Entacapone Orion are a fixed combination of levodopa, carbidopa and entacapone, ATC Code N04BA03. Levodopa is a dopaminergic agent that mediates the antiparkinsonian effect by converting to dopamine in the brain through decarboxylation. Carbidopa, a dopa decarboxylase (DDC) inhibitor, and entacapone, a catechol-O-methyl transferase (COMT) inhibitor, both modify the therapeutic properties of levodopa by modifying the peripheral metabolism of levodopa, in order to improve its availability to the brain, but have no therapeutic activity without levodopa.

The benefits with Levodopa/Carbidopa/Entacapone Orion as a fixed combination product would be, primarily, a simplification of therapy of patients with a fluctuating Parkinson's disease. The reduction of the number of tablets to be swallowed is clinically relevant in advanced Parkinson's disease patients, who may have difficulties in swallowing and who often have to take multiple drugs. The most common side effects are dyskinesia, gastrointestinal symptoms including nausea and diarrhoea, and muscle, musculoskeletal and connective tissue pain.

The approved indication is: "Levodopa/Carbidopa/Entacapone Orion is indicated for the treatment of adult patients with Parkinson's disease and end-of-dose motor fluctuations not stabilised on levodopa/dopa decarboxylase (DDC) inhibitor treatment".

[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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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.

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