19 September 2013
EMA/CHMP/364817/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Levodopa Carbidopa Entacapone Sandoz

Levodopa carbidopa entacapone

On 19 September 2013, 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 Sandoz, 50 mg / 12.5 mg / 200 mg; 75 mg / 18.75 mg / 200 mg; 100 mg / 25 mg / 200 mg; 125 mg / 31.25 mg / 200 mg; 150 mg / 37.5 mg / 200 mg; 175 mg / 43.75 mg / 200 mg and 200 mg / 50 mg / 200 mg; Film-coated tablet; intended 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.

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 Levodopa Carbidopa Entacapone Sandoz is Levodopa /Carbidopa /Entacapone, a combination of an immediate precursor of dopamine, a Dopa Decarboxylase inhibitor (carbidopa) and a COMT (Catechol-O-methyltransferase) inhibitor (entacapone). The addition of carbidopa to levodopa increases its availability into the brain resulting in the possibility to decrease the levodopa dose by an average of 75%. The use of entacapone together with the two other components enhances the availability of levodopa into the brain and allows to avoid the peripheral side effects of levodopa.

The most common side effects are: Muscle, musculoskeletal and connective tissue pain, Diarrhoea, Nausea, Chromaturia and Dyskinesia.

A pharmacovigilance plan for Levodopa Carbidopa Entacapone Sandoz will be implemented as part 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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The approved indication is: "Levodopa/Carbidopa/Entacapone Sandoz 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".

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 Levodopa Carbidopa Entacapone Sandoz and therefore recommends the granting of the marketing authorisation.