18 November 2010
EMA/CHMP/659548/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Entacapone Teva

entacapone

On *18 November 2010* 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 Teva*, 20*0 mg, Film-coated tablets. Entacapone Teva 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. The applicant for this medicinal product is Teva Pharma 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 Entacapone Teva is entacapone, an other dopaminergic agent (N04BX02) which prolongs the clinical response to levodopa. This is achieved by decreasing the metabolic loss of levodopa to 3-O-methyldopa (3-OMD) by inhibiting the COMT enzyme, which in turn leads to a higher levodopa AUC. Thus the amount of levodopa available to the brain is increased.

Entacapone Teva is a generic of Comtess, which has been authorised in the EU since 16-09-1998. Studies have demonstrated the satisfactory quality of Entacapone Teva, and its bioequivalence with the reference product Comtess. A question and answer document on generic medicines can be found here.

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

The approved indication is: 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

[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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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 Entacapone Teva and therefore recommends the granting of the marketing authorisation.