21 July 2011
EMA/CHMP/507521/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Pramipexole Accord

pramipexole

On 21 July 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 Pramipexole Accord, 0.088 mg, 0.18 mg, 0.35 mg, 0.7 mg and 1.1 mg, tablets intended for the treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations). Pramipexole Accord is also indicated in adults for symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in doses up to 0.54 mg of base (0.75 mg of salt).

The applicant for this medicinal product is Accord Healthcare Ltd. 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 Pramipexole Accord is pramipexole as dihydrochloride monohydrate, which is a dopamine agonist (N04BC05) that binds with high selectivity and specificity to the D_2 subfamily of dopamine receptors of which it has a preferential affinity to D_3 receptors, and has full intrinsic activity. Furthermore, pramipexole alleviates Parkinsonian motor Symptoms by stimulation of dopamine receptors in the striatum. Animal studies have shown that pramipexole inhibits the dopamine synthesis, release, and turnover.

Pramipexole Accord is a generic of Mirapexin which has been authorised in the EU since 23 February 1998. Studies have demonstrated the satisfactory quality of Pramipexole Accord, and its bioequivalence with Mirapexin. A question-and-answer document on generic medicines can be found here.

The approved indication is: Pramipexole Accord is indicated in adults for treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa,

[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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i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or “on off” fluctuations).

Pramipexole Accord is indicated in adults for symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in doses up to 0.54 mg of base (0.75 mg of salt).

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 that there is a favourable benefit to risk balance for Pramipexole Accord and therefore recommends the granting of the marketing authorisation.