17 December 2015
EMA/CHMP/558150/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Neofordex

dexamethasone

On 17 December 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Neofordex, intended for the treatment of symptomatic multiple myeloma. Neofordex was designated as an orphan medicinal product on 9 June 2010. The applicant for this medicinal product is Laboratoires CTRS.

Neofordex will be available as a 40-mg tablet. The active substance of Neofordex is dexamethasone acetate, a corticosteroid for systemic use (ATC code: H02AB02).

The benefits with dexamethasone are its ability to improve survival and response in combination with other medicinal products in symptomatic multiple myeloma. The most common side effects are hyperglycaemia, insomnia, muscle pain and weakness, asthenia, fatigue, oedema and weight increase.

The full indication is: "Neofordex is indicated in adults for the treatment of symptomatic multiple myeloma in combination with other medicinal products." It is proposed that Neofordex must be initiated and monitored under the supervision of physicians experienced in the management of multiple myeloma.

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.

[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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