27 June 2024
EMA/CHMP/281252/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nilotinib Accord

nilotinib

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nilotinib Accord, intended for the treatment of chronic myelogenous leukaemia (CML). The applicant for this medicinal product is Accord Healthcare S.L.U.

Nilotinib Accord will be available as 50 mg, 150 mg and 200 mg hard capsules. The active substance of Nilotinib Accord is nilotinib, an antineoplastic protein kinase inhibitor (ATC code: L01EA03) that inhibits the activity of BCR-ABL kinase and other selected oncogenic kinases.

Nilotinib Accord is a generic of Tasigna, which has been authorised in the EU since 19 November 2007. Studies have demonstrated the satisfactory quality of Nilotinib Accord, and its bioequivalence to the reference product Tasigna. A question and answer document on generic medicines can be found here.

The full indication is:

> Nilotinib Accord is indicated for the treatment of:
>
> - adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase,
> - adult patients with chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available,
> - paediatric patients with chronic phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib.

Nilotinib Accord should be prescribed by physicians experienced in the treatment of patients with CML.

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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