27 January 2022
EMA/CHMP/10836/2022
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Dasatinib Accord

dasatinib



On 27 January 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dasatinib Accord, intended for the treatment of Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL). The applicant for this medicinal product is Accord Healthcare S.L.U.

Dasatinib Accord will be available as 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg film-coated tablets. The active substance of Dasatinib Accord is dasatinib, a protein kinase inhibitor (ATC code: L01EA02) that potently inhibits the activity of the BCR-ABL tyrosine kinase (TK) as well as several receptor TKs.

Dasatinib Accord is a generic of Sprycel, which has been authorised in the EU since 20 November 2006. Studies have demonstrated the satisfactory quality of Dasatinib Accord, and its bioequivalence to the reference product Sprycel. A question and answer document on generic medicines can be found here.

The full indication is:

Dasatinib Accord is indicated for the treatment of adult patients with:

- Ph+ acute lymphoblastic leukaemia (ALL) with resistance or intolerance to prior therapy.

Dasatinib Accord is indicated for the treatment of paediatric patients with:

- newly diagnosed Ph+ ALL in combination with chemotherapy.

Dasatinib Accord should be prescribed by physicians experienced in the treatment of leukaemia.

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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