



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 May 2024  
EMA/CHMP/233375/2024  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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# Dasatinib Accord Healthcare

## dasatinib

On 30 May 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 Dasatinib Accord Healthcare, intended for the treatment of adults with chronic myelogenous leukaemia (CML).

The applicant for this medicinal product is Accord Healthcare S.L.U.

Dasatinib Accord Healthcare will be available as 20, 50, 70, 80, 100 and 140 mg film-coated tablets. The active substance of Dasatinib Accord Healthcare is dasatinib, an antineoplastic agent, protein kinase inhibitor (ATC code: L01EA02). Dasatinib inhibits the activity of BCR-ABL and SRC kinases, as well as other oncogenic kinases including c-KIT, ephrin (EPH) receptor kinases, and PDGF $\beta$  receptor.

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

- newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase.
- chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib.
- Ph+ acute lymphoblastic leukaemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.

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

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



- newly diagnosed Ph+ CML in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib.
- newly diagnosed Ph+ ALL in combination with chemotherapy.

Dasatinib Accord Healthcare should be prescribed by physicians experienced in the diagnosis and treatment of patients with 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.