27 January 2022
EMA/CHMP/10901/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dasatinib Accordpharma

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 Accordpharma, intended for the treatment of chronic myeloid leukaemia (CML) and Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL). The applicant for this medicinal product is Accord Healthcare S.L.U.

Dasatinib Accordpharma 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 Accordpharma 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 Accordpharma is a generic of Sprycel, which has been authorised in the EU since 22 November 2006. Studies have demonstrated the satisfactory quality of Dasatinib Accordpharma, 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 Accordpharma 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 Accordpharma is indicated for the treatment of paediatric patients with:

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- 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 Accordpharma 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.