



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2025
EMA/CHMP/86912/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Bosulif bosutinib

On 27 March 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Bosulif. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted a change to the existing indications to extend the use of Bosulif to children aged 6 years and older with certain types of chronic myelogenous leukaemia, along with a new pharmaceutical form, hard capsules, associated with two new strengths, 50 mg and 100 mg. The full indications for Bosulif will therefore be as follows:²

Bosulif is indicated for the treatment of ~~adult patients with~~:

- **Adult and paediatric patients aged 6 years and older with** newly-diagnosed (ND) chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML).
- **Adult and paediatric patients aged 6 years and older with CP Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) [TKI(s)] and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.**
- **Adult patients with** ~~CP~~, accelerated phase (AP), and blast phase (BP) Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) [TKI(s)] and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to 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

² New text in bold, removed text as strikethrough

