



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2026
EMADOC-1700519818-3162552
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Iclusig ponatinib

On 21 May 2026, 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 Iclusig. The marketing authorisation holder for this medicinal product is Incyte Biosciences Distribution B.V.

The CHMP adopted a new indication associated with a new pharmaceutical form and a new strength, 5 mg hard capsule, as follows:

Iclusig is indicated as monotherapy in paediatric patients 6 years of age or older with

- chronic phase chronic myeloid leukaemia (CP-CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

For information, the full indications for Iclusig will be as follows:²

Iclusig is indicated **as monotherapy** in adult patients with

- chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation
- Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

Iclusig is indicated in combination with reduced-intensity chemotherapy in adult patients with newly diagnosed Ph+ ALL (see section 5.1).

Iclusig is indicated as monotherapy in paediatric patients 6 years of age or older with

- **chronic phase chronic myeloid leukaemia (CP-CML) who are resistant to dasatinib**

¹ Summary 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



or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

See sections 4.2 for the assessment of cardiovascular status prior to start of therapy and 4.4 for situations where an alternative treatment may be considered.

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.