29 January 2026
EMADOC-1700519818-2832341
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Iclusig

ponatinib

On 29 January 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 as follows:[2]

> Iclusig is indicated 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).**
>
> 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.

[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

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