26 February 2026
EMADOC-1700519818-2935903
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Scemblix

asciminib

On 26 February 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 Scemblix. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted a new strength, 100 mg film-coated tablets, associated with a new indication, as follows:[2]

> Scemblix is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) (see section 5.1).
>
> **Scemblix is indicated for the treatment of adult patients with Ph+ CML-CP with the T315I mutation who are resistant to, intolerant to or ineligible for ponatinib (see section 5.1).**

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] 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

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