



14 September 2017
EMA/CHMP/595185/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tasigna

nilotinib

On 14 September 2017, 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 Tasigna. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd.

The CHMP adopted an extension to the existing indication as follows:²

“Tasigna is indicated for the treatment of:

- adult **and paediatric** patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase,
- adult patients with chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available,
- **paediatric patients with chronic phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib.**”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available 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

