13 November 2025
EMA/CHMP/348586/2025
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Koselugo

selumetinib

On 13 November 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 Koselugo. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a new pharmaceutical form, granules in capsules for opening, in two strengths (5 mg and 7.5 mg), associated with an extension to the existing indication, as follows:[2]

> Koselugo as monotherapy is indicated for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in patients with neurofibromatosis type 1 (NF1) aged **1 year to less than 7 years and for older patients with swallowing difficulties**.

This indication only applies to the pharmaceutical form granules in capsules for opening. For information on the indication for each pharmaceutical form, please refer to the summary of product characteristics (SmPC).

Detailed recommendations for the use of this product will be described in the updated 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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