18 September 2025
EMADOC-1700519818-2413725
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Koselugo

selumetinib

On 18 September 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 change to the existing indication as follows:[2]

> Koselugo as monotherapy is indicated for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in **adult and** paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and **older**~~above~~.

For information, the full indication for Koselugo will be as follows:

> Koselugo as monotherapy is indicated for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in adult and paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and older.

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, removed text as strikethrough

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union