17 September 2026
EMADOC-1700519818-3429729
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pepaxti

melphalan flufenamide

On 17 September 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 Pepaxti. The marketing authorisation holder for this medicinal product is Oncopeptides AB.

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

> Pepaxti is indicated, in combination with dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least ~~three~~ **two** prior lines of therapies, whose disease is refractory to ~~at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD30 monoclonal antibody,~~ **lenalidomide** and ~~who have demonstrated disease progression on or after~~ the last **line of** therapy. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation (see section 4.4).

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, 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