21 May 2026
EMADOC-1700519818-3182005
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Palynziq

pegvaliase

On 21 May 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 Palynziq. The marketing authorisation holder for this medicinal product is Biomarin International Limited.

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

> Palynziq is indicated for the treatment of patients with phenylketonuria (PKU) aged ~~16~~ **12** years and older who have inadequate blood phenylalanine control (blood phenylalanine levels greater than 600 micromol/l) despite prior management with available treatment options.

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.

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