16 October 2025
EMA/329333/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pyrukynd

mitapivat

On 16 October 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 Pyrukynd. The marketing authorisation holder for this medicinal product is Agios Netherlands B.V.

The CHMP adopted a new indication associated with a new strength, 100 mg film-coated tablets, as follows[2]:

> **Pyrukynd is indicated in adults for the treatment of anaemia associated with transfusion-dependent and non-transfusion-dependent alpha- or beta-thalassaemia (see section 5.1).**

For information, the indication for Pyrukynd 5 mg, 20 mg and 50 mg film-coated tablets is as follows:

> Pyrukynd is indicated for the treatment of pyruvate kinase deficiency (PK deficiency) in adult patients (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] 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] 2 New text in bold

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