23 April 2026
EMA/84334/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Palbociclib Viatris

palbociclib

On 23 April 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Palbociclib Viatris, intended for the treatment of locally advanced or metastatic breast cancer.

The applicant for this medicinal product is Viatris Limited.

Palbociclib Viatris will be available as 75 mg, 100 mg and 125 mg film-coated tablets. The active substance of Palbociclib Viatris is palbociclib, an antineoplastic agent, protein kinase inhibitor (ATC code: L01EF01). Palbociclib is a highly selective, reversible inhibitor of cyclin-dependent kinases (CDK) 4 and 6. Cyclin D1 and CDK4/6 are downstream of multiple signalling pathways which lead to cellular proliferation.

Palbociclib Viatris is a generic of Ibrance, which has been authorised in the EU since 9 November 2016. Studies have demonstrated the satisfactory quality of Palbociclib Viatris, and its bioequivalence to the reference product Ibrance. A question and answer document on generic medicines can be found here.

The full indication will be as follows:

> Palbociclib Viatris is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.
>
> - in combination with an aromatase inhibitor;
> - in combination with fulvestrant in women who have received prior endocrine therapy (see section 5.1).
>
> In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

Treatment with Palbociclib Viatris should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.

[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

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.