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Palbociclib Viatris (*palbociclib*)

A plain-language overview of Palbociclib Viatris and why it is authorised in the EU

What is Palbociclib Viatris and what is it used for?

Palbociclib Viatris is a cancer medicine used to treat breast cancer when the cancer is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body). Palbociclib Viatris can only be used when the cancer cells have receptors (targets) for certain hormones on their surface (HR-positive) and do not produce abnormally large quantities of a receptor called HER2 (HER [human epidermal growth factor] negative). Palbociclib Viatris is used in the following ways:

- together with an aromatase inhibitor (a hormonal medicine for cancer);
- together with fulvestrant (another hormonal medicine for cancer) in patients who have previously been treated with a hormonal medicine.

In women who have not yet reached menopause, a medicine called a luteinising hormone-releasing hormone agonist should also be given.

Palbociclib Viatris contains the active substance palbociclib and is a 'generic medicine'. This means that Palbociclib Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Palbociclib Viatris is Ibrance. For more information on generic medicines, see the question-and-answer document here.

How is Palbociclib Viatris used?

Palbociclib Viatris can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the use of cancer medicines.

Palbociclib Viatris is available as tablets taken by mouth. It should be taken once a day for 21 consecutive days, followed by a 7-day break to complete a 28-day treatment cycle. Treatment should continue for as long as the patient is benefitting from it and side effects are tolerable. If the patient experiences certain side effects, treatment may need to be interrupted or stopped, or the dose reduced.

For more information about using Palbociclib Viatris, see the package leaflet or contact your doctor or pharmacist.

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How does Palbociclib Viatris work?

The active substance in Palbociclib Viatris, palbociclib, blocks the activity of enzymes known as cyclin-dependent kinases (CDK) 4 and 6, which play a key role in regulating the way cells grow and divide. In some cancers, including HR-positive breast cancer, the activity of CDK 4 and 6 is increased, which helps the cancer cells to multiply uncontrollably. By blocking CDK4 and CDK6, Palbociclib Viatris slows the growth of HR-positive breast cancer cells.

How has Palbociclib Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Ibrance, and do not need to be repeated for Palbociclib Viatris.

As for every medicine, the company provided studies on the quality of Palbociclib Viatris. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the side effects and restrictions with Palbociclib Viatris?

Because Palbociclib Viatris is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Palbociclib Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Palbociclib Viatris has been shown to have comparable quality and to be bioequivalent to Ibrance. Therefore, the Agency's view was that, as for Ibrance, the benefits of Palbociclib Viatris outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Palbociclib Viatris?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Palbociclib Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Ibrance also apply to Palbociclib Viatris where appropriate.

As for all medicines, data on the use of Palbociclib Viatris are continuously monitored. Side effects reported with Palbociclib Viatris are carefully evaluated and any necessary action taken to protect patients.

Other information about Palbociclib Viatris

Palbociclib Viatris received a marketing authorisation valid throughout the EU on 19 June 2026.

Further information on Palbociclib Viatris, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/palbociclib-viatris. Information on the reference medicine can also be found on the Agency's website.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 06-2026.