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Ibrance (*palbociclib*)

An overview of Ibrance and why it is authorised in the EU

What is Ibrance and what is it used for?

Ibrance 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). Ibrance 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). Ibrance 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.

Ibrance contains the active substance palbociclib.

How is Ibrance used?

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

Ibrance is available as capsules and tablets (75 mg, 100 mg and 125 mg). The recommended dose is 125 mg once a day for 21 consecutive days, followed by a 7-day break to complete a 28-day treatment cycle. Treatment should be taken at around the same time each day. The capsules should be taken with food while the tablets can be taken with or without food. 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 Ibrance, see the package leaflet or contact your doctor or pharmacist.

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How does Ibrance work?

The active substance in Ibrance, 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, Ibrance slows the growth of HR-positive breast cancer cells.

What benefits of Ibrance have been shown in studies?

Ibrance has been studied in two main studies of women with HR-positive, HER2-negative breast cancer. In both studies, the main measure of effectiveness was how long patients lived without their disease getting worse (progression-free survival).

The first study involved 521 women with metastatic breast cancer that had got worse after treatment with a hormonal medicine. They received either Ibrance and fulvestrant or a placebo (dummy medicine) and fulvestrant. Women taking Ibrance and fulvestrant lived on average 11.2 months without their disease getting worse compared with 4.6 months for women taking placebo and fulvestrant.

The second study involved 666 women who had been through the menopause and whose breast cancer had started to spread and who had not yet received cancer treatment. They received either Ibrance and letrozole (an aromatase inhibitor) or placebo and letrozole. Women taking Ibrance and letrozole lived on average 24.8 months without their disease getting worse compared with 14.5 months for women taking placebo and letrozole.

What are the risks associated with Ibrance?

The most common side effects with Ibrance (which may affect more than 1 in 5 people) are neutropenia (low blood levels of neutrophils, a type of white blood cell that fights infection), infections, leucopenia (low white blood cell counts), tiredness, nausea (feeling sick), stomatitis (inflammation of the lining of the mouth), anaemia (low red blood cell counts), diarrhoea, alopecia (hair loss) and thrombocytopenia (low blood platelet counts).

The most common severe side effects with Ibrance (which may affect up to 1 in 50 people) are neutropenia, leucopenia, infections, anaemia, tiredness and increased blood levels of liver enzymes (aspartate and alanine transaminases).

For the full list of side effects of Ibrance, see the package leaflet.

Ibrance must not be used by patients who are taking St John's wort (a herbal preparation used to treat depression). For the full list of restrictions, see the package leaflet.

Why is Ibrance authorised in the EU?

Ibrance has been shown to prolong the time patients live without their disease getting worse by an average of 6 to 10 months, which is considered of clear clinical value. Regarding safety, the main risk is neutropenia, which is a well-known risk of many cancer medicines and is considered manageable.

The European Medicines Agency therefore decided that Ibrance's benefits are greater than its risks and that it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ibrance have been included in the summary of product characteristics and the package leaflet.

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

Other information about Ibrance

Ibrance received a marketing authorisation valid throughout the EU on 9 November 2016.

Further information on Ibrance can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ibrance.

This overview was last updated in 01-2020.