

IBRANCE® FILM COATED TABLETS

Palbociclib (75 mg, 100 mg and 125 mg)

What is in this leaflet

1. What Ibrance is used for
2. How Ibrance works
3. Before you use Ibrance
4. How to use Ibrance
5. While you are using it
6. Side effects
7. Storage and Disposal of Ibrance
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What Ibrance is used for

Ibrance is a prescription medicine used to treat hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic) in combination with:

- an aromatase inhibitor as the first hormonal based therapy in women who have gone through menopause, or
- fulvestrant in women with disease progression following hormonal therapy

How Ibrance works

Ibrance belongs to the group of medicines called antineoplastics. Ibrance interferes with the growth of cancer cells, which are eventually destroyed.

Before you use Ibrance

- When you must not use it

It is not known if Ibrance is safe and effective in children.

Pregnancy and lactation

Do not take Ibrance if you are pregnant, trying to get pregnant or think you may be pregnant.

Ibrance can harm your unborn baby. Females who are able to become pregnant and who take Ibrance should use effective birth control during treatment and for at least 3 weeks after stopping Ibrance.

The male partner of the female patient (who are able to become pregnant) should also use effective birth control during treatment and for at least 3 weeks after stopping Ibrance.

Talk to your healthcare provider about birth control methods that may be right for you during this time.

If you become pregnant or think you are pregnant, tell your healthcare provider right away.

It is not known if Ibrance passes into your breast milk. Do not take Ibrance if you are breast-feeding or plan to breastfeed, at least for 3 weeks after the last dose.

- Before you start to use it

Tell your doctor if you:

- have fever, chills, dizziness, weakness, any increased tendency to bleed and/or to bruise or any other signs or symptoms of infection.
- experience shortness of breath, restlessness, cough or any respiratory symptoms.
- have liver or kidney problems.
- have signs of blood clots in the vein (venous thromboembolism).
- have any other medical conditions.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription medicines, over-the-counter drugs, vitamins, and herbal products.

Some foods and other types of drugs can affect how CYP3A enzymes work. This can change the amount of cancer drug that you absorb. So it changes the dose of cancer drug that your doctor prescribed for you. This can affect how your cancer drug works, making it stronger or weaker.

You should inform your doctor if you are taking medicines containing:

- ketoconazole, itraconazole, voriconazole, posaconazole (used to treat fungal infections);
- clarithromycin, rifampin, telithromycin (used to treat infections);
- ritonavir, lopinavir/ritonavir, indinavir, nelfinavir, saquinavir, telaprevir (used to treat viral infections);
- modafinil (used to treat excessive sleepiness);
- phenytoin, carbamazepine (used to treat epilepsy and other neurological conditions);
- herbal preparations containing St. John's Wort (*Hypericum perforatum*) (used to treat depression and anxiety);
- cyclosporine, everolimus, sirolimus or tacrolimus (to prevent transplant rejection);
- midazolam (used to help you sleep or for anxiety);
- pimozone (used for treating mental illness);
- alfentanil, fentanyl (used as anaesthetic);
- quinidine (used for treating heart arrhythmia);
- ergotamine, dihydroergotamine (used to treat severe, throbbing headaches);
- nefazodone (used to treat depression);
- enzalutamide (used to treat prostate cancer).

How to use Ibrance

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Take one Tablet of Ibrance 125 mg orally once a day for 21 consecutive days, followed by

IBRANCE® FILM COATED TABLETS

Palbociclib (75 mg, 100 mg and 125 mg)

7 days without Ibrance. Your doctor may adjust your dose as needed and tolerated.

If you have reached menopause, Ibrance should be taken in combination with recommended dose of an aromatase inhibitor.

If you are having disease progression in spite of hormonal therapy, Ibrance should be taken in combination with fulvestrant, the recommended dose of fulvestrant is 500 mg to be taken on days 1, 15, 29 and once in a month thereafter.

If you have not reached menopause or reaching menopause and taking Ibrance plus fulvestrant therapy, then you should take luteinizing hormone releasing hormone (LHRH) agonists.

If you are already using a group of medicines called strong CYP3A inhibitors your Ibrance dose will be reduced to 75 mg once daily.

If you have severe liver problems, the recommended dose of Ibrance is 75 mg once daily for 21 consecutive days followed by 7 days off treatment.

If you develop respiratory problems such as; Interstitial Lung Disease (ILD) which is a severe life threatening disease characterized by scarring of the lungs, making it difficult to breathe or Pneumonitis which is the inflammation of the lungs; your doctor may immediately stop Ibrance.

- When to use it

Use as directed by your doctor or pharmacist.

You may take the Tablet with or without food. However, try to take it at the same time each day. This will help you to remember to take it.

- How long to use it

Continue taking Ibrance for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. If you miss a dose of Ibrance or vomit after taking a dose of Ibrance, do not take another dose. Take your next dose at your regular time.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Ibrance.

Tell your doctor immediately if you become pregnant while taking this medication.

Ibrance Tablets should be swallowed whole with a glass of water. Do not chew, crush or split them prior to swallowing.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Ibrance to anyone else, even if they have the same symptoms or condition as you.

Do not take any Tablets that have broken cracked or otherwise not intact.

Do not consume grapefruit products while on treatment with Ibrance.

- Things to be careful of

Driving and using machines

No studies on the effects of Ibrance on the ability to drive or operate machinery have been conducted. However, patients experiencing fatigue while taking Ibrance should exercise caution when driving or operating machinery.

Side effects

Like all medicines, Ibrance can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Ibrance may cause serious side effects, including:

Low white blood cell counts (neutropenia).

Low white blood cell counts are common when taking Ibrance. Your healthcare provider should check your white blood cell counts before and during treatment.

If you develop low white blood cell counts during treatment with Ibrance, your healthcare provider may stop your treatment, decrease your dose, or may tell you to wait to begin your treatment cycles.

Infection in lungs (ILD/Pneumonitis).

A severe, life threatening infection developed in the lungs. If you experience cough along with shortness of breath or lack of oxygen characterized by confusion, restlessness or anxiety, immediately visit your doctor.

Your doctor will immediately stop Ibrance if you develop any new or worsening respiratory disease.

IBRANCE® FILM COATED TABLETS

Palbociclib (75 mg, 100 mg and 125 mg)

Other common side effects of Ibrance include:

- tiredness
- fever
- nausea
- lost sense of taste
- unusual hair thinning or hair loss
- diarrhea
- decreased appetite
- vomiting
- inflammation of the mouth and lips
- low blood platelet (certain type of blood cell) count
- leukopenia (decrease in white blood cells)
- weakness
- rash
- dry skin
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- redness, pain, peeling, swelling and blistering of palms of hands and/or soles of feet (Palmar-Plantar Erythrodysesthesia Syndrome [PPES])
- increased blood creatinine

Other side effects of Ibrance include:

- signs of blood clots in the vein (venous thromboembolism) such as pain or stiffness, swelling and redness in the affected leg (or arm), chest pain, shortness of breath, lightheadedness, rapid breathing or rapid heart rate

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Ibrance

- Storage

Keep out of the reach and sight of children.

Store below 30°C

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how

to dispose of medicines no longer required. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help to protect the environment.

Product Description

- What it looks like

Box containing either a blister pack of 7 tablets each, or three blister packs of 7 tablets each (21 tablets total)

Tablet Strength 125 mg:

Oval, light purple, film-coated tablets debossed with “Pfizer” on one side and “PBC 125” on the other side.

Tablet Strength 100 mg:

Oval, green, film-coated tablets debossed with “Pfizer” on one side and “PBC 100” on the other side.

Tablet Strength 75 mg:

Round, light purple, film-coated tablets debossed with “Pfizer” on one side and “PBC 75” on the other side.

- Ingredients

- Active Ingredient:
Palbociclib

- Inactive ingredients:
Microcrystalline cellulose, colloidal silicon dioxide, crospovidone, magnesium stearate, succinic acid, hypromellose, titanium dioxide, triacetin, and FD&C Blue #2/Indigo Carmine Aluminum Lake.

In addition, the 75 mg and 125 mg tablets contain red iron oxide and the 100 mg tablets contain yellow iron oxide.

- MAL number

Ibrance Film-coated Tablets 125 mg- MAL23096010AZ

Ibrance Film-coated Tablets 100 mg- MAL23096009AZ

Ibrance Film-coated Tablets 75 mg- MAL23096008AZ

Manufacturer

Pfizer Manufacturing Deutschland GmbH,
Mooswaldallee 1,
79108 Freiburg Im Breisgau,
Germany.

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11,
Wisma Averis, Tower 2,
Avenue 5, Bangsar South,
No. 8 Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

Date of Revision

07/07/2025

Serial Number

NPRA (R1/4) 21052025/081

PLD-IBRANCE-0725