Package leaflet: Information for the patient

IBRANCE 75 mg hard capsules
IBRANCE 100 mg hard capsules
IBRANCE 125 mg hard capsules
palbociclib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What IBRANCE is and what it is used for

IBRANCE is an anticancer medicine containing the active substance palbociclib.

Palbociclib works by blocking proteins called cyclin-dependent kinase 4 and 6, which regulate cell growth and division. Blocking these proteins can slow down growth of cancer cells and delay the progression of your cancer.

IBRANCE is used to treat patients with certain types of breast cancer (hormone receptor-positive, human epidermal growth factor receptor 2-negative) which have spread beyond the original tumour and/or to other organs. It is given together with aromatase inhibitors or fulvestrant, which are used as hormonal anticancer therapies.

2. What you need to know before you take IBRANCE

Do not take IBRANCE

- if you are allergic to palbociclib or any of the other ingredients of this medicine (listed in section 6).
- use of preparations containing St. John’s Wort should be avoided while you are taking IBRANCE.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking IBRANCE.

IBRANCE may reduce the number of your white blood cells and weaken your immune system. Therefore, you may be at greater risk of getting an infection while you are taking IBRANCE.

Tell your doctor, pharmacist or nurse if you experience signs or symptoms of an infection, such as chills or fever.

You will have regular blood tests during treatment to check whether IBRANCE affects your blood cells (white blood cells, red blood cells, and platelets).

IBRANCE may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms including:

- difficulty breathing or shortness of breath
- dry cough
- chest pain

Children and adolescents

IBRANCE is not to be used in children or adolescents (under 18 years of age).

Other medicines and IBRANCE

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. IBRANCE may affect the way some other medicines work.

In particular, the following may increase the risk of side effects with IBRANCE:

- Lopinavir, indinavir, nelfinavir, ritonavir, telaprevir, and saquinavir used to treat HIV infection/AIDS.
- Clarithromycin and telithromycin antibiotics used to treat bacterial infections.
- Voriconazole, itraconazole, ketoconazole, and posaconazole used to treat fungal infections.
- Nefazodone used to treat depression.

The following medicines may have increased risk of side effects when given with IBRANCE:

- Quinidine generally used to treat heart rhythm problems.
- Colchicine used to treat gout.
- Pravastatin and rosuvastatin used to treat high cholesterol levels.
- Sulfasalazine used to treat rheumatoid arthritis.
- Alfentanil used for anaesthesia in surgery; fentanyl used in pre-procedures as a pain reliever as well as an anaesthetic.
- Cyclosporine, everolimus, tacrolimus, and sirolimus used in organ transplantation to prevent rejection.
- Dihydroergotamine and ergotamine used to treat migraine.
- Pimozide used to treat schizophrenia and chronic psychosis.

The following medicines may reduce the effectiveness of IBRANCE:

- Carbamazepine and phenytoin, used to stop seizures or fits.
- Enzalutamide to treat prostate cancer.
- Rifampin used to treat tuberculosis (TB).
- St. John’s Wort, a herbal product used to treat mild depression and anxiety.

IBRANCE with food and drink

Avoid grapefruit and grapefruit juice while you are taking IBRANCE as it may increase the side effects of IBRANCE.

Pregnancy and breast-feeding and fertility

You should not use IBRANCE if you are pregnant.

You should avoid becoming pregnant while taking IBRANCE.

Discuss contraception with your doctor if there is any possibility that you or your partner may become pregnant.

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Women of childbearing potential who are receiving this medicinal product, or their male partners should use adequate contraceptive methods (e.g., double-barrier contraception such as condom and diaphragm). These methods should be used during therapy and for at least 3 weeks after completing therapy for females and for at least 14 weeks for males.

Breast-feeding
You should not breast-feed while taking IBRANCE. It is not known if IBRANCE is excreted in breast milk.

Fertility
Palbociclib may decrease fertility in men.

Therefore, men may consider sperm preservation before taking IBRANCE.

Driving and using machines

Tiredness is a very common side effect. If you feel unusually tired, take special care when driving or using machines**.**

IBRANCE contains lactose
This medicine contains lactose (found in milk or dairy products). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sodium

This medicinal product contains less than 1 mmol (23 mg) sodium per capsule, that is to say essentially ‘sodium-free’.

3. How to take IBRANCE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 125 mg of IBRANCE taken once a day for 3 weeks followed by 1 week without taking IBRANCE. Your doctor will tell you how many capsules of IBRANCE to take.

If you experience certain side effects while you are taking IBRANCE (see section 4 “Possible side effects”), your doctor may lower your dose or stop treatment, either temporarily or permanently. The dose may be lowered to one of the other available strengths 100 mg or 75 mg.

Take IBRANCE once a day at about the same time every day with food, preferably a meal.

Swallow the capsule whole with a glass of water. Do not chew or crush the capsules. Do not open the capsules.

If you take more IBRANCE than you should

If you have taken too much IBRANCE, see a doctor or go to a hospital immediately. Urgent treatment may be necessary.

Take the carton and this leaflet, so that the doctor knows what you have been taking.

If you forget to take IBRANCE

If you miss a dose or vomit, take your next dose as scheduled. Do not take a double dose to make up for the forgotten capsules.

If you stop taking IBRANCE

Do not stop taking IBRANCE unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them:

Contact your doctor immediately if you have any of these symptoms:

- fever, chills, weakness, shortness of breath, bleeding, or easy bruising which could be a sign of a serious blood disorder.
- difficulty breathing, dry cough or chest pain which could be a sign of inflammation of the lungs.

Other side effects with IBRANCE may include:

Very common side effects (may affect more than 1 in 10 people):

Infections
Reduction in white blood cells, red blood cells, and blood platelets
Feeling of tiredness
Decreased appetite
Inflammation of the mouth and lips (stomatitis), nausea, vomiting, diarrhoea
Rash
Hair loss
Weakness
Fever
Abnormalities in liver blood tests
Dry skin

Common side effects (may affect up to 1 in 10 people):

Fever with a drop in the white blood cell count (febrile neutropenia)
Blurred vision, increased tearing, dry eye
Alteration in taste (dysgeusia)
Nosebleed

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme

website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store IBRANCE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle or blister and carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What IBRANCE contains
- The active substance is palbociclib. IBRANCE hard capsules come in different strengths.
- IBRANCE 75 mg hard capsule: each capsule contains 75 mg palbociclib.
- IBRANCE 100 mg hard capsule: each capsule contains 100 mg palbociclib.
- IBRANCE 125 mg hard capsule: each capsule contains 125 mg palbociclib.
- The other ingredients are:
  Capsule content: microcrystalline cellulose, lactose monohydrate, sodium starch glycolate type A, colloidal anhydrous silica, magnesium stearate. Capsule shell: gelatin, red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171). Printing ink: shellac, titanium dioxide (E171), ammonium hydroxide (28% solution), propylene glycol, simeticone (see section 2 "IBRANCE contains lactose and sodium").

What IBRANCE looks like and contents of the pack
- IBRANCE 75 mg is supplied as opaque, hard capsules, with a light orange body (printed "PBC 75" in white) and a light orange cap (printed "Pfizer" in white).
- IBRANCE 100 mg is supplied as opaque, hard capsules, with a light orange body (printed "PBC 100" in white) and a caramel cap (printed "Pfizer" in white).
- IBRANCE 125 mg is supplied as opaque, hard capsules, with a caramel body (printed "PBC 125" in white) and a caramel cap (printed "Pfizer" in white).

IBRANCE 75 mg, 100 mg and 125 mg are available in blister packs of 21 or 63 hard capsules and in plastic bottles of 21 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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