Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Ibrance® 75 mg
Ibrance® 100 mg
Ibrance® 125 mg
Capsules

Each capsule contains:
palbociclib 75 mg, 100 mg or 125 mg

List of inactive ingredients and allergens in the preparation: see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.
This medicine is intended for adult women over the age of 18.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Ibrance® is intended for the treatment of estrogen receptor-positive and HER2-negative advanced or metastatic breast cancer, in combination with:

- An aromatase inhibitor as the first (endocrine-based) combination therapy in postmenopausal women.

Or

- Fulvestrant in women with disease progression following previous endocrine therapy.

Therapeutic group: antineoplastic, kinase inhibitor.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine listed in section 6 "Further information" in this leaflet.

Special warnings about using this medicine:
Before treatment with Ibrance®, tell your doctor if:

- you have fever, chills, or any other symptom of infection.
- you have impaired liver or kidney function.
- you have any other medical condition.
- you are pregnant or plan to become pregnant. This medicine may harm your unborn baby.
  - Women who are able to become pregnant and are taking this medicine should use effective birth control during treatment and for three weeks after completing treatment with Ibrance®.
  - Consult with your doctor about birth control methods that may be right for you during this time.
  - If you become pregnant or suspect you are pregnant, tell your doctor right away.
- you are breastfeeding or plan to breastfeed: It is not known if this medicine passes into breast milk. You should speak to your doctor about whether to take the medicine or breastfeed. Do not do both. Also, do not breastfeed for 3 weeks after stopping treatment with Ibrance®.

Children
The safety and effectiveness of the medicine in children have not been studied.

Tests and follow-up
Your doctor will make sure to perform blood tests before and during use of the medicine.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Especially if you are taking:

- Medicines that may significantly increase Ibrance® level in the blood: clarithromycin, telithromycin (antibiotic); itraconazole, ketoconazole, posaconazole, voriconazole (to treat fungal infection); lopinavir/ritonavir, indinavir, nelfinavir, saquinavir (to treat the AIDS virus); telaprevir (to treat hepatitis); nefazodone (to treat depression). Avoid using these preparations during treatment with Ibrance®.
- Medicines that may significantly decrease Ibrance® level in the blood: rifampicin (to treat tuberculosis); phenytoin, carbamazepine (to treat epilepsy); *Hypericum* St. John's Wort (to treat depression); enzalutamide (for prostate cancer); modafinil (to treat sleep disturbances). Avoid using these preparations during treatment with Ibrance®.
- Avoid eating grapefruits, products containing grapefruit and drinking grapefruit juice during the treatment period with Ibrance®. The combination may increase the concentration of the medicine in your blood.
- Ibrance® may increase the blood concentrations of the following medicines: midazolam (to treat epilepsy), cyclosporine, sirolimus, tacrolimus (to suppress the immune system), ergot derivatives (e.g., ergotamine, dihydroergotamine), everolimus (to treat cancer and suppress the immune system), fentanyl, alfentanil (to relieve intense pain/as an anesthetic), pimozide (neuroleptic), quinidine (to regulate heart rhythm disturbances).

Using this medicine and food
Take the medicine with a meal.

Avoid drinking grapefruit juice or eating grapefruits during treatment with Ibrance®.

Pregnancy and breastfeeding
- If you are pregnant, or plan to become pregnant, this medicine may harm your unborn baby.
  - Women who are able to become pregnant and are taking this medicine should use effective birth control during treatment and for three weeks after completing treatment with Ibrance®.
  - Consult with your doctor about birth control methods that may be right for you during this time.
  - If you become pregnant or suspect you are pregnant, tell your doctor right away.
- If you are breastfeeding or plan to breastfeed: It is not known if this medicine passes into breast milk. You should speak to your doctor about whether to take the medicine or breastfeed. Do not do both. Also, do not breastfeed for 3 weeks after stopping treatment with Ibrance®.

Important information about some of this medicine's ingredients
Ibrance® contains lactose and sodium.

This preparation 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.

This preparation contains less than 1 mmol (23 mg) sodium per capsule and that is to say it is essentially sodium free.

3. HOW TO USE THIS MEDICINE?
Always use this preparation according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by your doctor only. The standard dosage of Ibrance® is usually:
- one 125 mg capsule once a day, with a meal, for 21 consecutive days, followed by 7 days off treatment to complete a cycle of 28 days.
- When Ibrance® is given in combination with an aromatase inhibitor, take the standard dosage of the aromatase inhibitor. Refer to the aromatase inhibitor patient leaflet.
- When Ibrance® is given in combination with fulvestrant, the standard dosage of fulvestrant is 500 mg on days 1, 15 and 29 and once a month thereafter. Refer to the fulvestrant patient leaflet.

- **Do not exceed the recommended dose.**
- It is important to take the medicine at about the same time each day.
- How to use: Swallow the capsule whole. Do not chew, halve/open or crush the capsules.

- Do not change your dose or stop treatment with the medicine without being instructed to do so by your doctor.

If you have accidentally taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time or if you vomited after taking the dose, do not take an additional dose on that day. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ibrance®, may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Refer to a doctor immediately in the event of:

- **Decrease in white blood cell count in the blood circulation (neutropenia):** Decrease in white blood cell count in the blood is a very common condition when using this medicine. This condition can lead to serious infections, which can lead to death.
  Your doctor will monitor your white blood cell counts before and during treatment with this medicine. If you develop a decrease in white blood cell count during treatment with Ibrance®, your doctor may tell you to stop your treatment, decrease your dose, or wait to begin your next treatment cycle. Refer to your doctor immediately if you have symptoms of infection such as fever or chills.
- **Decrease in red blood cell count and decrease in platelet count in the blood circulation:** Decrease in red blood cell count and platelet count in the blood circulation is a common condition when using this medicine. Refer to a doctor immediately if you develop any of the following symptoms during treatment: dizziness, shortness of breath, weakness, increased tendency to bleed or bruise, nosebleed.
- **Lung problems (pneumonitis):** Ibrance® may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. Tell your doctor right away if you have any new or worsening symptoms, including: trouble breathing or shortness of breath, cough with or without mucus, chest pain.

Additional common side effects:
Neutropenia, thrombocytopenia, anemia, dry skin, taste disturbance, tiredness, infections, nausea, rash, inflammation and pain in the mouth, thinner hair or hair loss, diarrhea, reduced/lack of appetite, vomiting, weakness, leukopenia, fever.

Additional side effects: Blurred vision, dry eye, increased tearing, nosebleed, febrile neutropenia, abnormalities in blood tests of liver enzymes.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 30°C.
- Do not use this medicine if you notice capsules that are broken/cracked/appear damaged.
- Shelf life after first opening: 6 months.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, hard gelatin capsule shell and printing ink. The hard gelatin capsule shell contains gelatin, red iron oxide, yellow iron oxide and titanium dioxide.

Ibrance® 75 mg capsule contains 55.77 mg lactose monohydrate.
Ibrance® 100 mg capsule contains 74.37 mg lactose monohydrate.
Ibrance® 125 mg capsule contains 92.96 mg lactose monohydrate.

What the medicine looks like and contents of the pack:
Ibrance® 125 mg: opaque, caramel-colored capsule, with the word “Pfizer” imprinted in white on the upper part and “PBC 125” on the lower part.
Ibrance® 100 mg: opaque capsule, whose upper part is caramel-colored, with “Pfizer” imprinted in white and an orange lower part, with “PBC 100” imprinted on it.
Ibrance® 75 mg: opaque, orange-colored capsule, with the word “Pfizer” imprinted in white on the upper part and “PBC 75” on the lower part.

Each bottle contains 21 capsules.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration numbers of the medicines in the Ministry of Health’s National Drug Registry:
Ibrance® 75 mg: 156-88-34525
Ibrance® 100 mg: 156-89-34528
Ibrance® 125 mg: 156-90-34529

Revised in 11/2021 according to MoH guidelines.