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# **Package Leaflet: Information for the user**

## **Palbociclib Capsules – 75 mg, 100 mg, 125 mg**

### **PALBACE®**

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

- If you have any further questions, ask your doctor.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Palbace (Palbociclib) is and what it is used for
2. What you need to know before you take Palbace (Palbociclib)
3. How to take Palbace (Palbociclib)
4. Possible side effects
5. How to store Palbace (Palbociclib)
6. Contents of the pack and other information

#### **1. What Palbace (Palbociclib) is and what it is used for**

Palbace (Palbociclib) is an anticancer medicine containing the active substance palbociclib.

Palbace (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.

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## **For Women:**

Palbace (Palbociclib) is used to treat women 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 in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone releasing hormone (LHRH) agonist.

## **For Men:**

Palbace (Palbociclib) is used to treat men 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.

If you have any questions about how Palbace (Palbociclib) works or why this medicine has been prescribed for you, ask your doctor.

## **2. What you need to know before you take Palbace (Palbociclib)**

### **Do not take Palbace (Palbociclib)**

- 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, an herbal product should be avoided while you are taking Palbace (Palbociclib).

### **Warnings and precautions**

#### **Talk to your doctor before taking Palbace (Palbociclib):**

Palbace (Palbociclib) 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 Palbace (Palbociclib).

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

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

Palbace (Palbociclib) may increase your liver or kidney impairment; tell your doctor, if you observe any worsening symptoms.

Palbace (Palbociclib) may cause severe or life-threatening inflammation of the lungs, weakness and raised temperature 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

### Critical visceral disease

The efficacy and safety of palbociclib have not been studied in patients with critical visceral disease.

### **Children and adolescents**

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

### **Other medicines and Palbace (Palbociclib)**

Tell your doctor if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription and even those not prescribed.

In particular, the following may increase the risk of side effects with Palbace (Palbociclib):

- Lopinavir, indinavir, nelfinavir, ritonavir, telaprevir, and saquinavir.
- Clarithromycin and telithromycin antibiotics.
- Voriconazole, itraconazole, ketoconazole, and posaconazole.
- Nefazodone.

The following medicines may have increased risk of side effects when given with Palbace (Palbociclib):

- Quinidine.
- Colchicine.
- Pravastatin and rosuvastatin.
- Sulfasalazine.
- Alfentanil; fentanyl.
- Cyclosporine, everolimus, tacrolimus, and sirolimus.
- Dihydroergotamine and ergotamine.
- Pimozide.

Substrates of P-gp (e.g., digoxin, dabigatran)

The following medicines may reduce the effectiveness of Palbace (Palbociclib):

- Carbamazepine and phenytoin.
- Enzalutamide.
- Rifampin.
- St. John's Wort, an herbal product.

### **Palbace (Palbociclib) with food and drink**

Palbace (Palbociclib) capsules may be taken with food, preferably a meal to ensure consistent palbociclib exposure.

Avoid grapefruit and grapefruit juice while you are taking Palbace (Palbociclib) as it may increase the side effects of Palbace (Palbociclib).

### **Pregnancy and breast-feeding**

You should not use Palbace (Palbociclib) if you are pregnant.

You should avoid becoming pregnant while taking Palbace (Palbociclib).

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 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). 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 Palbace (Palbociclib). It is not known if Palbace (Palbociclib) is excreted in breast milk.

### **Fertility**

Palbace (Palbociclib) may decrease fertility in men.

Therefore, men may consider sperm preservation before taking Palbace (Palbociclib).

### **Driving and using machines**

Tiredness is a very common side effect of Palbace (Palbociclib). If you feel unusually tired, take special care when driving or using machines.

### **Palbace (Palbociclib) contains sodium**

This medicine contains less than 1 mmol (23 mg) sodium per capsule, that is to say essentially 'sodium-free'.

## Lactose

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take this medicine.

### **3. How to take Palbace (Palbociclib)**

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

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

If you experience certain side effects while you are taking Palbace (Palbociclib) (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 Palbace (Palbociclib) once a day at about the same time every day with or without food.

Swallow the capsule whole with a glass of water. Do not chew or crush the capsules. Do not split the capsules prior to swallowing. No capsule should be ingested if it is broken, cracked, or otherwise not intact.

Palbace (Palbociclib) can be taken with food, preferably a meal to ensure consistent palbociclib exposure.

#### **If you take more Palbace (Palbociclib) than you should**

If you have taken too much Palbace (Palbociclib), 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 Palbace (Palbociclib)**

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 Palbace (Palbociclib)**

Do not stop taking Palbace (Palbociclib) unless your doctor tells you to.

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

### **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, raised temperature and weakness.

Other side effects with Palbace (Palbociclib) 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
- Inflammation of the lung tissue

#### **Uncommon side effects (may affect up to 1 in 100 people):**

- Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints and fever (Cutaneous Lupus Erythematosus [CLE]).

## 5. How to store Palbace (Palbociclib)

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 “EXPIRY”. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original blister package, below 30°C.

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 doctor 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 Palbace (Palbociclib) contains

- The active substance is Palbociclib. Palbace (Palbociclib) capsules come in different strengths:
  - PALBACE 75 mg capsule: Each hard capsule contains 75 mg Palbociclib.
  - PALBACE 100 mg capsule: Each hard capsule contains 100 mg Palbociclib.
  - PALBACE 125 mg capsule: Each hard capsule contains 125 mg Palbociclib.
- The other ingredients are:  
Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, and hard gelatin capsule shells. The light orange, light orange/caramel and caramel opaque capsule shells contain gelatin, red iron oxide, yellow iron oxide, and titanium dioxide; and the printing ink contains shellac, titanium dioxide, ammonium hydroxide, propylene glycol and simethicone.

### What Palbace (Palbociclib) looks like and contents of the pack

- Palbace (Palbociclib) 75 mg capsules: Size #2, opaque, hard capsule, with a light orange body color (printed “PBC 75” in white) and a light orange cap color (printed “Pfizer” in white). The capsule contains an off-white to yellow powder.
- Palbace (Palbociclib) 100 mg capsules: Size #1, opaque, hard capsule, with a light orange body color (printed “PBC 100” in white) and a caramel cap color (printed “Pfizer” in white). The capsule contains an off-white to yellow powder.
- Palbace (Palbociclib) 125 mg capsules: Size #0, opaque, hard capsule, with a caramel body color (printed “PBC 125” in white) and a caramel cap color (printed “Pfizer” in white). The capsule contains an off-white to yellow powder.

21 capsules in high-density polyethylene (HDPE) bottles with polypropylene (PP) closures and heat induction seal liners.

07 capsules per blister pack of Polyvinyl Chloride (PVC)/PCTFE/PVC films with aluminium foil lidding; 1 blister per carton.

07 capsules per blister pack of Polyvinyl Chloride (PVC)/PCTFE/PVC films with aluminium foil lidding; 3 blisters per carton.

All strengths/pack sizes mentioned in this document might not be available in the market.

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