

Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user

Palbociclib Tablets - 75 mg, 100 mg, 125 mg

PALBACE®

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)
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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. It is given together with aromatase inhibitor as initial endocrine-based therapy and with fulvestrant in patients who have received prior therapy. 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 blood clots in the veins. Tell your doctor, pharmacist or nurse if you experience signs or symptoms of blood clots in the veins such as pain or stiffness, swelling and redness in the affected leg (or arm), chest pain, shortness of breath or lightheadedness.

Palbace (Palbociclib) 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
- raised temperature

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 generally.
- Colchicine.
- Pravastatin, simvastatin, atorvastatin, fluvastatin and rosuvastatin, increased risk of rhabdomyolysis with concomitant use of Palbace (Palbociclib) and statins due to increased statin plasma concentration.
- Sulfasalazine.
- Alfentanil; fentanyl.
- Cyclosporine, everolimus, tacrolimus, and sirolimus.
- Dihydroergotamine and ergotamine.
- Pimozide.
- 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) tablets may be taken with or without food.

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.

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

Palbace (Palbociclib) can be taken with or without food.

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 tablets.

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, weakness and raised temperature.

- painful swollen leg, chest pain, shortness of breath, rapid breathing or rapid heart rate as these can be signs of blood clots in the vein (which may affect up to 1 in 10 people).

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
- Redness, pain, peeling, swelling and blistering of palms of hands and/or soles of feet (Palmar-Plantar Erythrodysesthesia Syndrome [PPES])
- Abnormal kidney blood test result (high level of creatinine in the blood)

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]).
- A skin reaction that causes red spots or patches on the skin that may look like a target or “bulls eye” with a dark red centre surrounded by paler red rings (erythema multiforme).

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 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 in order to protect from moisture.

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) film-coated tablets come in different strengths:
 - PALBACE 75 mg: Each film-coated tablet contains 75 mg Palbociclib.
 - PALBACE 100 mg: Each film-coated tablet contains 100 mg Palbociclib.
 - PALBACE 125 mg: Each film-coated tablet contains 125 mg Palbociclib.
- The other ingredients are:
Tablet core: microcrystalline cellulose, colloidal silicon dioxide, crospovidone, magnesium stearate, succinic acid.
Film-coating: hypromellose (E464), titanium dioxide (E171), triacetin, FD&C Blue #2/
Indigo carmine aluminum lake (E132), iron oxide red (E172) (75 mg and 125 mg tablets only), iron oxide yellow (E172) (100 mg tablets only).

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

- Palbace (Palbociclib) 75 mg tablets are supplied as round, light purple, film-coated tablets with “Pfizer” on one side and “PBC 75” on the other side.
- Palbace (Palbociclib) 100 mg tablets are supplied as oval, green, film-coated tablets with “Pfizer” on one side and “PBC 100” on the other side.
- Palbace (Palbociclib) 125 mg tablets are supplied as oval, light purple, film-coated tablets with “Pfizer” on one side and “PBC 125” on the other side.

Palbace (Palbociclib) 75 mg, 100 mg, and 125 mg are available as pack of 21 tablets in total. It contains 3 blister packs of 7 tablets each.

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

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