

PACKAGE LEAFLET

Package leaflet: Information for the user
Palsiva 75 mg film-coated tablets
Palsiva 100 mg film-coated tablets
Palsiva 125 mg film-coated tablets
palbociclib

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 [Product Name] is and what it is used for
2. What you need to know before you take [Product Name]
3. How to take [Product Name]
4. Possible side effects
5. How to store [Product Name]
6. Contents of the pack and other information

1. What [Product Name] is and what it is used for

[Product Name] 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.

[Product Name] 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 [Product Name]

Do not take [Product Name]

- 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 used to treat mild depression and anxiety, should be avoided while you are taking [Product Name].

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking [Product Name].

[Product Name] 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 [Product Name].

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 [Product Name] affects your blood cells (white blood cells, red blood cells, and platelets).

[Product Name] 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.

[Product Name] 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

[Product Name] is not to be used in children or adolescents (under 18 years of age).

Other medicines and [Product Name]

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

In particular, the following may increase the risk of side effects with [Product Name]:

- 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 [Product Name]:

- Quinidine generally used to treat heart rhythm problems.
- Colchicine used to treat gout.
- Pravastatin, simvastatin, atorvastatin, fluvastatin 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 [Product Name]:

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

[Product Name] with food and drink

[Product Name] tablets may be taken with or without food.

Avoid grapefruit and grapefruit juice while you are taking [Product Name] as it may increase the side effects of [Product Name].

Pregnancy and breast-feeding and fertility

You should not use [Product Name] if you are pregnant.

You should avoid becoming pregnant while taking [Product Name].

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 [Product Name]. It is not known if [Product Name] is excreted in breast milk.

Fertility

Palbociclib may decrease fertility in men.

Therefore, men may consider sperm preservation before taking [Product Name].

Driving and using machines

Tiredness is a very common side effect of [Product Name]. If you feel unusually tired, take special care when driving or using machines.

3. How to take [Product Name]

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 [Product Name] taken once a day for 3 weeks followed by 1 week without taking [Product Name]. Your doctor will tell you how many tablets of [Product Name] to take.

If you experience certain side effects while you are taking [Product Name] (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 [Product Name] 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.

If you take more [Product Name] than you should

If you have taken too much [Product Name], 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 [Product Name]

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 [Product Name]

Do not stop taking [Product Name] 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.
- 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 [Product Name] 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
- 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).

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 [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product Name]

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

This medicinal product 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 [Product Name] contains

- The active substance is palbociclib. [Product Name] film-coated tablets come in different strengths:
 - [Product Name] 75 mg film-coated tablet: each tablet contains 75 mg palbociclib.
 - [Product Name] 100 mg film-coated tablet: each tablet contains 100 mg palbociclib.
 - [Product Name] 125 mg film-coated tablet: each tablet contains 125 mg palbociclib.
- The other ingredients are:
 Tablet core: microcrystalline cellulose; silica, colloidal anhydrous; crospovidone; magnesium stearate; gluconolactone; glutamic acid.
 Film-coating: hypromellose (E464); titanium dioxide (E171); triacetin; 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 [Product Name] looks like and contents of the pack

- [Product Name] 75 mg tablets are supplied as round, 10.3 mm, light purple to purple, film-coated tablets debossed with “771” on one side and plain on the other side.
- [Product Name] 100 mg tablets are supplied as oval, 15.0 x8.0 mm, light green to green, film-coated tablets debossed with “772” on one side and plain on the other side.
- [Product Name] 125 mg tablets are supplied as oval, 16.2 x8.6 mm, light purple to purple, film-coated tablets debossed with “773” on one side and plain on the other side.

[Product Name] 75 mg, 100 mg, and 125 mg are available in blister packs of 21 tablets or 63 tablets in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

<This medicine is authorised in the Member States of the European Economic Area <and in the United Kingdom (Northern Ireland)> under the following names:>

[To be completed nationally]

This leaflet was last revised in 2026-02-11