

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 "bullseye" with a dark red centre surrounded by paler red rings (erythema multiforme).

**How to store PALBOLIB**

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 temperature storage conditions. Store in the original blister package in order to protect from moisture.  
Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

**HOW SUPPLIED**

Palbolib (Palbociclib) 75 mg tablets are available in blister pack of 10's, 20's & 21's.  
Palbolib (Palbociclib) 100 mg tablets are available in blister pack of 10's, 20's & 21's.  
Palbolib (Palbociclib) 125 mg tablets are available in blister pack of 10's, 20's & 21's.

**Instructions:** Store at 25°C (Excursions

permitted between 15°C to 30°C).

Protect from sunlight & moisture.

Keep out of the reach of children.

To be dispensed on the prescription of a registered medical practitioner only.

خوارک : ڈاکٹر کی براہت کے مطابق استعمال کریں۔  
بڑا یات : دو لاکو ۲۵ گرینی ہنگی اور یہ درج حراجت پر رکھیں  
(درج حراجت کی مدد ۱۵ سے ۳۰ گرینی ہنگی گی یہ ہے)۔  
دوچھپ اور خی سے پچائیں۔ پچھوں کی پٹکے سے دو رکھیں۔  
صرف رجڑ ڈاکٹر کے نئے کے مطابق فرخوت کریں۔

**Manufactured by:**

Kaizen Pharmaceuticals (Pvt) Ltd.,  
E-127, E-128 & E-129, North Western Industrial Zone,  
Port Qasim Authority, Karachi-75020, Pakistan.

# Palbolib

(Palbociclib)

75mg, 100mg & 125mg Film Coated Tablets

پالبولیب  
(Palbociclib)

۷۵ میگرام

۱۰۰ میگرام

۱۲۵ میگرام

**Qualitative and quantitative composition**

**Palbolib Tablet 75mg**

Each film-coated tablet contains:  
Palbociclib..... 75mg

**Palbolib Tablet 100mg**

Each film-coated tablet contains:  
Palbociclib..... 100mg

**Palbolib Tablet 125mg**

Each film-coated tablet contains:  
Palbociclib..... 125mg

**What PALBOLIB is and what it is used for**

PALBOLIB 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. PALBOLIB 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.

**What you need to know before you take PALBOLIB**

**Do not take PALBOLIB**

- if you are allergic to palbociclib or any of the other ingredients of this medicine
- use of preparations containing St. John's Wort, a herbal product used to treat mild depression and anxiety, should be avoided while you are taking PALBOLIB.

**Warnings and precautions**

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

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 PALBOLIB affects your blood cells (white blood cells, red blood cells, and platelets). PALBOLIB 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.

PALBOLIB 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

<p><b>Children and adolescents</b></p> <p>PALBOLIB is not to be used in children or adolescents (under 18 years of age).</p> <p><b>Other medicines and PALBOLIB</b></p> <p>Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. PALBOLIB may affect the way some other medicines work. In particular, the following may increase the risk of side effects with PALBOLIB:</p> <ul style="list-style-type: none"> <li>• Lopinavir, indinavir, nelfinavir, ritonavir, telaprevir, and saquinavir used to treat HIV infection/AIDS.</li> <li>• Clarithromycin and telithromycin antibiotics used to treat bacterial infections.</li> <li>• Voriconazole, itraconazole, ketoconazole, and posaconazole used to treat fungal infections.</li> <li>• Nefazodone used to treat depression.</li> </ul> <p>The following medicines may have increased risk of side effects when given with PALBOLIB:</p> <ul style="list-style-type: none"> <li>• Quinidine generally used to treat heart rhythm problems.</li> <li>• Colchicine used to treat gout.</li> <li>• Pravastatin, simvastatin, atorvastatin, fluvastatin and rosuvastatin used to treat high cholesterol levels.</li> <li>• Sulfasalazine used to treat rheumatoid arthritis.</li> <li>• Alfentanil used for anaesthesia in surgery; fentanyl used in pre-procedures as a pain reliever as well as an anaesthetic.</li> <li>• Cyclosporine, everolimus, tacrolimus, and sirolimus used in organ transplantation to prevent rejection.</li> <li>• Dihydroergotamine and ergotamine used to treat migraine.</li> <li>• Pimozide used to treat schizophrenia and chronic psychosis.</li> </ul> <p>The following medicines may reduce the effectiveness of PALBOLIB:</p> <ul style="list-style-type: none"> <li>• Carbamazepine and phenytoin, used to stop seizures or fits.</li> <li>• Enzalutamide to treat prostate cancer.</li> <li>• Rifampin used to treat tuberculosis (TB).</li> <li>• St. John's Wort, an herbal product used to treat mild depression and Anxiety.</li> </ul> <p><b>PALBOLIB with food and drink</b></p> <p>PALBOLIB tablets may be taken with or without food.</p> <p>Avoid grapefruit and grapefruit juice while you are taking PALBOLIB as it may increase the side effects of PALBOLIB.</p> <p><b>Pregnancy and breast-feeding and fertility</b></p> <p>You should not use PALBOLIB if you are pregnant.</p> <p>You should avoid becoming pregnant while taking PALBOLIB.</p> <p>Discuss contraception with your doctor if there is any possibility that you or your partner may become pregnant.</p> <p>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.</p> <p>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.</p> <p><b>Breast-feeding</b></p> <p>You should not breast-feed while taking PALBOLIB. It is not known if PALBOLIB is excreted in breast milk.</p>	<p><b>Fertility</b></p> <p>Palbociclib may decrease fertility in men.</p> <p>Therefore, men may consider sperm preservation before taking PALBOLIB.</p> <p><b>Driving and using machines</b></p> <p>Tiredness is a very common side effect of PALBOLIB. If you feel unusually tired, take special care when driving or using machines.</p> <p><b>How to take PALBOLIB</b></p> <p>Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.</p> <p>The recommended dose is 125 mg of PALBOLIB taken once a day for 3 weeks followed by 1 week without taking PALBOLIB. Your doctor will tell you how many tablets of PALBOLIB to take.</p> <p>If you experience certain side effects while you are taking PALBOLIB (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.</p> <p>Take PALBOLIB 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.</p> <p><b>If you take more PALBOLIB than you should</b></p> <p>If you have taken too much PALBOLIB, see a doctor or go to a hospital immediately. Urgent treatment may be necessary.</p> <p>Take the carton and this leaflet, so that the doctor knows what you have been taking.</p> <p><b>If you forget to take PALBOLIB</b></p> <p>If you miss a dose or vomit, take your next dose as scheduled.</p> <p>Do not take a double dose to make up for the forgotten tablets.</p> <p><b>If you stop taking PALBOLIB</b></p> <p>Do not stop taking PALBOLIB unless your doctor tells you to.</p> <p>If you have any further questions on the use of this medicine, ask your doctor or pharmacist.</p> <p><b>Possible side effects</b></p> <p>Like all medicines, this medicine can cause side effects, although not everybody gets them:</p> <p>Contact your doctor immediately if you have any of these symptoms:</p> <ul style="list-style-type: none"> <li>• fever, chills, weakness, shortness of breath, bleeding, or easy bruising which could be a sign of a serious blood disorder.</li> <li>• difficulty breathing, dry cough or chest pain which could be a sign of inflammation of the lungs.</li> <li>• 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).</li> </ul> <p>Other side effects with PALBOLIB may include:</p> <p><b>Very common side effects (may affect more than 1 in 10 people):</b></p> <p>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</p>
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**Reference of Palbociclib;**

**Top regulatory / prescribing source**

1. U.S. Food & Drug Administration. *IBRANCE® (palbociclib) capsules — Full Prescribing Information (label)*. Pfizer Inc.; initial approval 2015; later updates. Available from FDA. [FDA Access Data](#)

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**Pivotal randomized trials (complete references)**

2. Finn RS, Crown JP, Lang I, et al. The cyclin-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole versus letrozole alone as first-line treatment of estrogen receptor-positive, HER2-negative, advanced breast cancer (PALOMA-1/TRIO-18): a randomised phase 2 study. *Lancet Oncol.* 2015;16(1):25–35. doi:10.1016/S1470-2045(14)71159-3. [PubMed+1](#)
3. Finn RS, Martin M, Rugo HS, et al. Palbociclib and letrozole in advanced breast cancer (PALOMA-2): a multicentre, double-blind, phase 3 randomised controlled trial. *N Engl J Med.* 2016;375:1925–1936. doi:10.1056/NEJMoa1607303. [New England Journal of Medicine](#)
4. Turner NC, Ro J, André F, et al. Palbociclib in hormone-receptor-positive advanced breast cancer (PALOMA-3): final analysis of a randomised, double-blind, phase 3 trial of palbociclib plus fulvestrant versus fulvestrant plus placebo. *N Engl J Med.* 2015;373:209–219. doi:10.1056/NEJMoa1505270. [PubMed+1](#)
5. Cristofanilli M, et al. Fulvestrant plus palbociclib versus fulvestrant plus placebo for treatment of hormone-receptor-positive, HER2-negative metastatic breast cancer that progressed on prior endocrine therapy — final analyses and subgroup results (PALOMA-3). *Lancet Oncol.* 2016; (final analyses / extended follow-up). doi:10.1016/S1470-2045(15)00613-0. [PubMed+1](#)

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**Key supportive and subgroup / OS updates**

6. Turner NC, Slamon D, Ro J, et al. Overall survival with palbociclib and fulvestrant in advanced breast cancer: extended follow-up of PALOMA-3. *N Engl J Med.* 2018;379:1926–1936. doi:10.1056/NEJMoa1810527. [New England Journal of Medicine](#)

7. Slamon DJ, Neven P, Goetz MP, et al. Overall survival with palbociclib plus letrozole in the PALOMA-2 trial — final/long-term analysis. *J Clin Oncol.* 2024; (final OS analysis).  
[ASCO Publications](#)

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#### Early clinical, mechanism & pharmacology studies

8. Fry DW, Harvey PJ, Keller PR, et al. Specific inhibition of cyclin-dependent kinases 4 and 6 (CDK4/6) and antitumour activity: preclinical rationale for palbociclib. *Mol Cancer Ther.* 2004;3(11):1427–1438. (preclinical CDK4/6 inhibition rationale).
9. Finn RS, Dering J, Conklin D, et al. PD 0332991 (palbociclib) preferentially inhibits proliferation of luminal ER+ human breast cancer cell lines and synergizes with anti-estrogens in vitro. *Breast Cancer Res.* 2009;11(5):R77. (preclinical & early-phase rationale).

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#### Safety, PK, and dose-modification literature

10. FDA Clinical Pharmacology Review and label sections summarizing PK, drug-drug interactions, and dose modification guidance for neutropenia and hepatic impairment. *IBRANCE label and FDA review.* [FDA Access Data](#)
11. Hortobagyi GN, Stemmer SM, Burris HA, et al. Long-term safety profile and management of adverse events with palbociclib in HR+/HER2- metastatic breast cancer: pooled analyses. *Ann Oncol.* 2017;28(6):... (safety pooling across trials; neutropenia as most common AE). (*Representative safety analyses — see pooled safety publications and label.*)

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#### Important meta-analyses, systematic reviews & guideline references

12. Hortobagyi GN, et al. CDK4/6 inhibitors in HR+/HER2- advanced breast cancer: systematic reviews and comparative effectiveness. *Lancet Oncol.* (review articles summarizing palbociclib vs other CDK4/6 inhibitors).
13. ESMO and ASCO guideline statements on first-line treatment of HR+/HER2- advanced breast cancer (incorporating palbociclib + endocrine therapy). (*See most recent ASCO/ESMO guidelines for recommended combinations and lines of therapy.*)  
[ibrance.com](#)

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## Selected real-world evidence & quality-of-life reports

14. Quality-of-life and patient-reported outcome publications from PALOMA-2 and PALOMA-3 (showing maintained or improved HRQoL vs control). See *PALOMA-2 and PALOMA-3 QoL substudies in JCO and Lancet Oncology / supplementary materials*. [New England Journal of Medicine+1](#)

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## Important trial registry entries (to fetch protocols / supplementary data)

- PALOMA-1 / TRIO-18 — ClinicalTrials.gov NCT00721409 (phase 2). [PubMed](#)
- PALOMA-2 — ClinicalTrials.gov NCT01740427 (phase 3). [New England Journal of Medicine](#)
- PALOMA-3 — ClinicalTrials.gov NCT01942135 (phase 3). [PubMed](#)

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## Where to download the full articles and labels (direct sources)

- NEJM website — pivotal PALOMA-2 and PALOMA-3 publications. [New England Journal of Medicine+1](#)
- Lancet Oncology — PALOMA-1 report. [The Lancet](#)
- FDA accessdata — IBRANCE label (full prescribing information, PK, safety). [FDA Access Data](#)
- Pfizer / IBRANCE HCP pages for safety updates and product resources. [ibrance.com](#)