

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** **S4****PALBOCICLIB CIPLA (75 mg, 100 mg, 125 mg capsules)****Palbociclib****Contains sugar:**

PALBOCICLIB 75 mg CIPLA: Lactose monohydrate (55,800 mg)

PALBOCICLIB 100 mg CIPLA: Lactose monohydrate (74,400 mg)

PALBOCICLIB 125 mg CIPLA: Lactose monohydrate (93,000 mg)

Read all of this leaflet carefully before you are given PALBOCICLIB CIPLA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PALBOCICLIB CIPLA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What PALBOCICLIB CIPLA is and what it is used for

PALBOCICLIB CIPLA 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 delays the progression of your cancer. PALBOCICLIB CIPLA is used to treat patients with certain types of breast cancer (hormone receptor [HR]-positive, human epidermal growth factor receptor [HERS] 2-negative) which have spread beyond the original tumour and/or to other organs. It is given together with letrozole as initial endocrine-based therapy in postmenopausal women or fulvestrant, which are used as hormonal anticancer therapies.

2. What you need to know before you take PALBOCICLIB CIPLA

Do not take PALBOCICLIB CIPLA

- if you are hypersensitive (allergic) to palbociclib or any of the other ingredients of this medicine (listed in section 6).
- use of preparations containing St. John's Wort should be avoided while you are taking PALBOCICLIB CIPLA.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking PALBOCICLIB CIPLA.

PALBOCICLIB CIPLA 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 PALBOCICLIB CIPLA.

Before you take PALBOCICLIB CIPLA

Tell your healthcare provider if you:

- have fever, chills, or any other signs or symptoms of infection.

- have liver or kidney problems.
- have any other medical conditions.
- are pregnant, or plan to become pregnant. PALBOCICLIB CIPLA can harm your unborn baby.

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

PALBOCICLIB CIPLA 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

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

Other medicines and PALBOCICLIB CIPLA

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines)

PALBOCICLIB CIPLA may affect the way some other medicines work. In particular, the following may increase the risk of side effects with PALBOCICLIB CIPLA:

- 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 PALBOCICLIB CIPLA:

- Quinidine generally used to treat heart rhythm problems.
- Colchicine used to treat gout.
- Pravastatin 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 PALBOCICLIB CIPLA:

- Carbamazepine, felbamate, phenobarbital, primidone and phenytoin, used to stop seizures or fits.
- Enzalutamide to treat prostate cancer.
- Rifampicin, rifapentine and rifabutin used to treat tuberculosis (TB).
- Nevirapine used to treat HIV
- St. John's Wort, a herbal product used to treat mild depression and anxiety.

PALBOCICLIB CIPLA with food and drink

Avoid grapefruit and grapefruit juice while you are taking PALBOCICLIB CIPLA as it may increase the side effects of PALBOCICLIB CIPLA.

Pregnancy and breastfeeding and fertility

Do not use PALBOCICLIB CIPLA if you are pregnant or breastfeeding your baby.

You should avoid becoming pregnant while taking PALBOCICLIB CIPLA.

Discuss contraception with your doctor if there is any possibility that you or your partner may become pregnant.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking PALBOCICLIB CIPLA.

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.

Breastfeeding

You should not breast-feed while taking PALBOCICLIB CIPLA. It is not known if PALBOCICLIB CIPLA is excreted in breast milk.

Fertility

Palbociclib may decrease fertility in men.

Therefore, men may consider sperm preservation before taking PALBOCICLIB CIPLA.

Driving and using machines

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

It is not always possible to predict to what extent PALBOCICLIB CIPLA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PALBOCICLIB CIPLA affects them.

PALBOCICLIB CIPLA contains lactose monohydrate

This medicine 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.

PALBOCICLIB CIPLA contains Sodium

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

3. How to take PALBOCICLIB CIPLA

Do not share medicines prescribed for you with any other person.

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 usual dose is 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment (Schedule 3/1) to comprise a complete cycle of 28 days.

When co-administered with PALBOCICLIB CIPLA, the recommended dose of letrozole is 2,5 mg taken orally once daily continuously throughout the 28-day cycle. Please refer to the patient information leaflet of letrozole.

When co-administered with PALBOCICLIB CIPLA, the recommended dose of fulvestrant is 500 mg administered intramuscularly on Days 1, 15, 29, and once monthly thereafter. Please refer to the patient information leaflet of fulvestrant.

Take PALBOCICLIB CIPLA once a day at about the same time every day with food, preferably a meal.

Avoid grapefruit and grapefruit products during treatment with PALBOCICLIB CIPLA. Grapefruit may increase the amount of PALBOCICLIB CIPLA in your blood.

Swallow the capsule whole with a glass of water. Do not chew or crush the capsules. Do not open the capsules.

If you take more PALBOCICLIB CIPLA than you should

In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control center.

Take the carton and this leaflet, so that the doctor knows what you have been taking.

If you forget to take PALBOCICLIB CIPLA

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 PALBOCICLIB CIPLA

Do not stop taking PALBOCICLIB CIPLA 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

PALBOCICLIB CIPLA can have side effects.

Not all side effects reported for PALBOCICLIB CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PALBOCICLIB CIPLA, please consult your healthcare provider for advice.

If any of the following happens, stop taking / using PALBOCICLIB CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,

- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to PALBOCICLIB CIPLA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- Low red blood cell counts, and low platelet counts are common with PALBOCICLIB CIPLA
- weakness
- nosebleeds
- infections

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Feeling of tiredness
- Decreased appetite
- Inflammation of the mouth and lips (stomatitis), nausea, vomiting, diarrhoea
- Rash
- Hair loss
- Fever
- Abnormalities in liver blood tests
- Dry skin
- Fever with a drop in the white blood cell count (febrile neutropenia)

- Blurred vision, increased tearing, dry eye
- Alteration in taste (dysgeusia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your healthcare professional. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of PALBOCICLIB CIPLA.

5. How to store PALBOCICLIB CIPLA

Store all medicines out of reach of children.

Store at or below 25 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PALBOCICLIB CIPLA contains

The active substance is Palbociclib.

The other ingredients are:

- Lactose Monohydrate (200 mesh)
- Microcrystalline Cellulose (Avicel pH 102)
- Sodium Starch Glycolate (Type A)

- Magnesium stearate (Vegetable Grade)
- Colloidal silicon dioxide (Aerosil)
- Iron oxide red
- Iron oxide yellow
- Titanium dioxide
- Gelatin
- Water
- Shellac
- Dehydrated Alcohol
- Isopropyl Alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia Solution
- Black Iron Oxide
- Potassium Hydroxide

What PALBOCICLIB CIPLA looks like and contents of the pack**PALBOCICLIB CIPLA 75 mg**

Yellow colour blend, filled in size '2' opaque, hard gelatin capsules, with light orange cap and body, printed with black ink "Cipla" on the cap and "75 mg" on the body.

PALBOCICLIB CIPLA 100 mg

Yellow colour blend, filled in size '1' opaque, hard gelatin capsules, with caramel cap and light orange body, printed with black ink "Cipla" on the cap and "100 mg" on the body

PALBOCICLIB CIPLA 125 mg

Yellow colour blend, filled in size '0' opaque, hard gelatin capsules, with caramel cap and body, printed with black ink "Cipla" on the cap and "125 mg" on the body

PALBOCICLIB CIPLA 75 mg, 100 mg and 125 mg capsules are packed in HDPE container of 21's with 33MM 400 Argus LOC Blue Child Resistant cap.

Holder of Certificate of Registration**CIPLA MEDPRO (PTY) LTD**

Parc du Cap

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Customer Care: 080 222 6662

This leaflet was last revised in

Not applicable

Registration number(s)

PALBOCICLIB 75 mg CIPLA: 56/26/0161

PALBOCICLIB 100 mg CIPLA: 56/26/0162

PALBOCICLIB 125 mg CIPLA: 56/26/0163

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.
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