

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PALBOCICLIB 75 mg TABLETS PFIZER

PALBOCICLIB 100 mg TABLETS PFIZER

PALBOCICLIB 125 mg TABLETS PFIZER

Palbociclib

Sugar-free

Read all of this leaflet carefully before you start taking PALBOCICLIB TABLETS PFIZER

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, or other health care provider.
- PALBOCICLIB TABLETS PFIZER 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 TABLETS PFIZER is and what it is used for
2. What you need to know before you take PALBOCICLIB TABLETS PFIZER
3. How to take PALBOCICLIB TABLETS PFIZER
4. Possible side effects
5. How to store PALBOCICLIB TABLETS PFIZER
6. Contents of the pack and other information

1. What PALBOCICLIB TABLETS PFIZER is and what it is used for

PALBOCICLIB TABLETS PFIZER is an anticancer medicine containing the active substance palbociclib.

PALBOCICLIB TABLETS PFIZER 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.

PALBOCICLIB TABLETS PFIZER is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination:

- with letrozole, as initial endocrine-based therapy in postmenopausal women
- with fulvestrant in women with disease progression who have received prior endocrine therapy

2. What you need to know before you take PALBOCICLIB TABLETS PFIZER

Do not take PALBOCICLIB TABLETS PFIZER:

- if you are hypersensitive (allergic) to palbociclib or any of the other ingredients of PALBOCICLIB TABLETS PFIZER (listed in section 6).
- if you are taking St. John's Wort (an herbal supplement used to treat mild depression and anxiety)

Warnings and precautions

Take special care with PALBOCICLIB TABLETS PFIZER:

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

PALBOCICLIB TABLETS PFIZER 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 TABLETS PFIZER.

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 PALBOCICLIB TABLETS PFIZER affects your blood cells (white blood cells, red blood cells, and platelets).

PALBOCICLIB TABLETS PFIZER 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 light-headedness.

PALBOCICLIB TABLETS PFIZER may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. Tell your health care 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

The safety and efficacy of PALBOCICLIB TABLETS PFIZER in children have not been established.

Other medicines and PALBOCICLIB TABLETS PFIZER

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Medicines that increase the risk of side effects with PALBOCICLIB TABLETS PFIZER

- Lopinavir, indinavir, nelfinavir, ritonavir, telaprevir, and saquinavir used to treat HIV infection/AIDS
- Clarithromycin and telithromycin antibiotic 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 TABLETS PFIZER

- 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 TABLETS PFIZER

- Carbamazepine and phenytoin used to stop seizures or fits.
- Enzalutamide to treat prostate cancer
- Rifampicin used to treat tuberculosis (TB)
- St. John's Wort, an herbal product used to treat mild depression and anxiety (see section 2)

PALBOCICLIB TABLETS PFIZER with food and drink

Take PALBOCICLIB TABLETS PFIZER with or without food.

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not use PALBOCICLIB TABLETS PFIZER if you are pregnant.

You should avoid becoming pregnant while taking PALBOCICLIB TABLETS PFIZER

Contraception

Women of childbearing potential who take PALBOCICLIB TABLETS PFIZER, as well as partners of women on PALBOCICLIB TABLETS PFIZER must use effective contraception during the therapy and for at least 14 weeks after PALBOCICLIB TABLETS PFIZER is discontinued.

Breastfeeding

You should not breast-feed while taking PALBOCICLIB TABLETS PFIZER. It is unknown whether PALBOCICLIB TABLETS PFIZER is excreted in breast milk.

Fertility

PALBOCICLIB TABLETS PFIZER may decrease fertility in men. Therefore, men may consider sperm preservation before taking PALBOCICLIB TABLETS PFIZER.

Driving and using machines

PALBOCICLIB TABLETS PFIZER may make you feel tired or dizzy, you should exercise caution when driving or operating machinery.

It is not always possible to predict to what extent PALBOCICLIB TABLETS PFIZER may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PALBOCICLIB TABLETS PFIZER affects you.

3. How to take PALBOCICLIB TABLETS PFIZER

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

Always take PALBOCICLIB TABLETS PFIZER exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is a 125 mg tablet taken orally once daily for 21 consecutive days followed by 7 days without taking PALBOCICLIB TABLETS PFIZER (Schedule 3/1) to comprise a complete cycle of 28 days. Your doctor will tell you how many tablets of PALBOCICLIB TABLETS PFIZER to take.

When co-administered with PALBOCICLIB TABLETS PFIZER, 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 TABLETS PFIZER, 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 your dose at approximately the same time each day. PALBOCICLIB TABLETS PFIZER can be taken with or without food. Swallow the tablet whole with a glass of water.

Your doctor may modify the dose of PALBOCICLIB TABLETS PFIZER based on your individual safety and tolerability profile, thus it is important to take PALBOCICLIB TABLETS PFIZER exactly as advised.

Your doctor will monitor your complete blood count before starting PALBOCICLIB TABLETS PFIZER and on day 15 of the first 2 cycles and adjust the dosage if required.

If you vomit after taking a dose, do not take another dose. You should take the next prescribed dose at the usual time. PALBOCICLIB TABLETS PFIZER tablets should be swallowed whole (do not chew, crush or split them prior to swallowing). No tablet should be ingested if it is broken, cracked, or otherwise not intact.

Special populations

Elderly population

No dose adjustment is necessary if you are 65 years of age or older.

Hepatic impairment

No dose adjustments are required if you have mild or moderate liver problems. If you have severe liver problems, the recommended dose of PALBOCICLIB TABLETS PFIZER is 75 mg once daily for 21 consecutive days followed by 7 days off treatment (Schedule 3/1) to comprise a complete cycle of 28 days.

Renal impairment

No dose adjustments are required if you have mild, moderate or severe kidney problems.

Paediatric population

The safety and efficacy of PALBOCICLIB TABLETS PFIZER in children and adolescents ≤ 18 years of age have not been established.

Your doctor will tell you how long your treatment with PALBOCICLIB TABLETS PFIZER will last. Do not stop treatment early. If you have the impression that the effect of PALBOCICLIB TABLETS PFIZER is too strong or too weak, tell your doctor or pharmacist.

If you take more PALBOCICLIB TABLETS PFIZER than you should

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

If you forget to take PALBOCICLIB TABLETS PFIZER

Do not take a double dose to make up for forgotten individual doses. You should take the next prescribed dose at the usual time.

4. Possible side effects

PALBOCICLIB TABLETS PFIZER can have side effects.

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

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

- Signs or symptoms of infection, such as fever or chills.

- Signs and symptoms of low red blood cell or blood platelet count, such as dizziness, shortness of breath, weakness, bleeding or easier formation of bruises and nose bleeding.
- 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.

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

Tell your doctor if you notice the following:

Frequent side effects

- decreased appetite
- metallic taste in the mouth
- blurred vision
- increased tearing
- dry eyes
- nose bleeds
- stomatitis (inflammation inside the mouth, mouth sores, mouth pain, sore throat and discomfort)
- nausea
- diarrhoea
- vomiting
- rash
- hair loss
- dry skin
- redness, pain, peeling, swelling and blistering of palms of hands and/or soles of feet (Palmar-Plantar Erythrodysesthesia Syndrome [PPES])
- tiredness

- weakness
- fever
- abnormalities in liver blood tests

Less frequent side effects

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

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 doctor or pharmacist. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PALBOCICLIB TABLETS PFIZER.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store PALBOCICLIB TABLETS PFIZER

- Store at or below 30 °C.
- Store all medicines out of reach of children.
- Store in the original blister packaging order to protect from moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.

- 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 TABLETS PFIZER contains

- The active substance is palbociclib.
 - PALBOCICLIB 75 mg TABLETS PFIZER: each film-coated tablet contains 75 mg palbociclib.
 - PALBOCICLIB 100 mg TABLETS PFIZER: each film-coated tablet contains 100 mg palbociclib.
 - PALBOCICLIB 125 mg TABLETS PFIZER: each film-coated tablet contains 125 mg palbociclib.
- The other ingredients are:
 - *Tablet core*: microcrystalline cellulose, colloidal silicon dioxide, crospovidone, magnesium stearate, and succinic 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 PALBOCICLIB TABLETS PFIZER looks like and contents of the pack

PALBOCICLIB 75 mg TABLETS PFIZER: Round light purple film-coated tablet with "Pfizer" debossed on one tablet face and "PBC 75" debossed on the opposite tablet face.

PALBOCICLIB 100 mg TABLETS PFIZER: Oval green film-coated tablet with "Pfizer" debossed on one tablet face and "PBC 100" debossed on the opposite tablet face.

PALBOCICLIB 125 mg TABLETS PFIZER: Oval light purple film-coated tablet with "Pfizer" debossed on one tablet face and "PBC 125" debossed on the opposite tablet face.

PVC/OPA/Al/PVC/Al blister card containing 7 film-coated tablets (1 film-coated tablet per cell). Each carton contains 21 film-coated tablets (3 blister cards per carton)

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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