PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PALBOCICLIB PFIZER 75 mg Capsules

PALBOCICLIB PFIZER 100 mg Capsules

PALBOCICLIB PFIZER 125 mg Capsules

Palbociclib

Contains sugar

Each PALBOCICLIB PFIZER 75 mg capsule contains 55,78 mg lactose monohydrate.

Each PALBOCICLIB PFIZER 100 mg capsule contains 74,37 mg lactose monohydrate.

Each PALBOCICLIB PFIZER 125 mg capsule contains 92,96 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking PALBOCICLIB 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 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 PFIZER is and what it is used for
2. What you need to know before you take PALBOCICLIB PFIZER
3. How to take PALBOCICLIB PFIZER
4. Possible side effects
5. How to store PALBOCICLIB PFIZER
6. Contents of the pack and other information

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

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

PALBOCICLIB 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 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 PFIZER

Do not take PALBOCICLIB PFIZER

- if you are hypersensitive (allergic) to palbociclib or any of the other ingredients of PALBOCICLIB PFIZER (listed in section 6).

Warnings and precautions

Take special care with PALBOCICLIB PFIZER

Tell your doctor, pharmacist or other health care provider if you have fever, chills or any other signs or symptoms of infection.

PALBOCICLIB 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 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

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

Other medicines and PALBOCICLIB PFIZER

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

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

Simultaneous administration with potent isoenzyme CYP3A inhibitors should be avoided.

- Lopinavir, indinavir, nelfinavir, ritonavir, telaprevir, and saquinavir used to treat HIV infection/AIDS
- Telithromycin – an antibiotic used to treat bacterial infections
- Voriconazole, itraconazole, ketoconazole, and posaconazole used to treat fungal infections
- Nefazodone used to treat depression

Medicines may have increased risk of side effects when given with PALBOCICLIB PFIZER

- Colchicine used to treat gout.
- Pravastatin, simvastatin, atorvastatin, fluvastatin and rosuvastatin used to treat high cholesterol levels
- Sulfasalazine used to treat rheumatoid arthritis.

Medicines that may reduce the effectiveness of PALBOCICLIB PFIZER

The concomitant administration with strong CYP3A inducers should be avoided.

- Phenytoin, carbamazepine used to stop seizures or fits

- Rifampicin used to treat tuberculosis (TB)
- St. John's Wort - a herbal product used to treat mild depression and anxiety

The concomitant administration with moderate CYP3A inducers should be avoided.

- Bosentan used to treat high blood pressure in the vessels that carry blood to the lungs
- Efavirenz used for the treatment and prevention of HIV-1 infection
- Modafinil used to treat excessive sleepiness
- Nafcillin - an antibiotic used to treat bacterial infections

PALBOCICLIB PFIZER with food and drink

During PALBOCICLIB PFIZER therapy, avoid eating grapefruit and products containing grapefruit. Grapefruit may increase your plasma concentration of PALBOCICLIB PFIZER.

Take PALBOCICLIB PFIZER with food.

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.

- PALBOCICLIB PFIZER may have an adverse effect on the foetus.
- Women of childbearing potential who take PALBOCICLIB PFIZER, as well as partners of women on PALBOCICLIB PFIZER must use effective contraception during the therapy and for at least 14 weeks after PALBOCICLIB PFIZER is discontinued.
- If you are breastfeeding or plan to breastfeed. It is unknown whether PALBOCICLIB PFIZER is excreted in human breast milk. Together with your doctor, you should decide whether you will continue the use of

PALBOCICLIB PFIZER or breastfeed. You should not do both concurrently.

Based on the results from animal studies, male fertility can be affected by PALBOCICLIB PFIZER therapy.

Driving and using machines

PALBOCICLIB 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 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 PFIZER affects you.

PALBOCICLIB PFIZER contains lactose

If you have a hereditary galactose intolerance (the body is unable to absorb certain sugars), Lapp lactase deficiency (the body is unable to digest milk and milk products due to lack of an enzyme) or glucose-galactose malabsorption (the body is unable to absorb certain sugars), you should not take PALBOCICLIB PFIZER.

PALBOCICLIB PFIZER contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take PALBOCICLIB PFIZER

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

Always take PALBOCICLIB PFIZER exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

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 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 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.

PALBOCICLIB PFIZER should be taken with food.

Take your dose at approximately the same time each day.

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

Your doctor will monitor your complete blood count before starting PALBOCICLIB 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 PFIZER capsules should be swallowed whole (do not chew, crush or open them prior to swallowing). No capsule 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 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 PFIZER in children and adolescents ≤ 18 years of age have not been established.

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

If you take more PALBOCICLIB 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 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 PFIZER can have side effects.

Not all side effects reported for PALBOCICLIB PFIZER are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PALBOCICLIB 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
- nose bleeds
- stomatitis (inflammation inside the mouth, mouth sores, mouth pain, sore throat and discomfort)
- nausea
- diarrhoea
- vomiting
- rash
- tiredness
- weakness
- fever
- blurred vision
- dry eyes
- metallic taste in the mouth

- dry skin
- abnormal kidney blood test result (high level of creatinine in the blood)
- redness, pain, peeling, swelling and blistering of palms of hands and/or soles of feet (Palmar-Plantar Erythrodysaesthesia Syndrome [PPES])

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]).
- 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).

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 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 PFIZER

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- 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 PFIZER contains

- The active substance is palbociclib.

PALBOCICLIB PFIZER 75 mg: each capsule contains 75 mg palbociclib.

PALBOCICLIB PFIZER 100 mg: each capsule contains 100 mg palbociclib.

PALBOCICLIB PFIZER 125 mg: each capsule contains 125 mg palbociclib.

- The other ingredients are microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, and hard gelatin capsule shells.
  - The light orange, light orange/caramel, and caramel opaque capsule shells contain gelatin, red iron oxide, yellow iron oxide, and titanium dioxide.
  - The printing ink contains shellac, titanium dioxide, isopropyl alcohol, ammonium hydroxide, n-butyl alcohol, propylene glycol, and simethicone.

What PALBOCICLIB PFIZER looks like and contents of the pack

PALBOCICLIB PFIZER 75 mg: opaque, hard capsule with a light orange body/ light orange cap capsule imprinted with “PBC 75” on the body and “Pfizer” on the cap, in white ink. The capsule contains off-white to yellow powder.

PALBOCICLIB PFIZER 100 mg: opaque, hard capsule with a light orange body/caramel cap capsule imprinted with “PBC 100” on the body and “Pfizer” on the cap, in white ink. The capsule contains off-white to yellow powder.

PALBOCICLIB PFIZER 125 mg: opaque, hard capsule with a caramel body/caramel cap capsule imprinted with “PBC 125” on the body and “Pfizer” on the cap, in white ink. The capsule contains off-white to yellow powder.

PALBOCICLIB PFIZER is packed in high-density polyethylene bottles with polypropylene closures and heat induction seal liners, in a pack size of 21 capsules or in polychlorotrifluoroethylene/aluminium foil blister system as a unit dose of 1 capsule per cell.

Holder of Certificate of Registration

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