Applicant: Dr Reddy's Laboratories **Product Name:** PALVORED **Dosage form and strength:** Capsules 75/100/125	MODULE 1 1.3.2

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PALVORED 75/ 100/ 125, Capsules

Palbociclib

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking PALVORED.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PALVORED 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 PALVORED is and what it is used for.

2. What you need to know before you take PALVORED.

3. How to take PALVORED.

4. Possible side effects.

5. How to store PALVORED.

6. Contents of the pack and other information.

1. What PALVORED is and what it is used for

PALVORED 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.

PALVORED 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 letrozole (an aromatase inhibitor~~s~~) or fulvestrant, which are used as hormonal anticancer therapies.

2. What you need to know before you take PALVORED

Do not take PALVORED:

- 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, a herbal product used to treat mild depression and anxiety, should be avoided while you are taking PALVORED.

Warnings and precautions

Take special care with PALVORED:

Tell your doctor, pharmacist, or healthcare provider if the following apply to you or the following complications occur due to PALVORED treatment:

If you are a pre/perimenopausal woman taking PALVORED in combination with aromatase inhibitor medicines.

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

PALVORED 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

PALVORED 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.

If you have moderate or severe liver problems.

If you have moderate or severe kidney problems.

If you are using CYP3A inducer medicines (Example: carbamazepine).

If you are using CYP3A inhibitor medicines (Example: itraconazole).

Children

- This medicine is not recommended for use in children or adolescents (18 years of age and under).

Other medicines and PALVORED

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). The use of PALVORED with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other health care professional for advice. Your doctor may need to change the dose of PALVORED or the other medicines.

In particular, the following may increase the risk of side effects with PALVORED:

• Lopinavir, indinavir, nelfinavir, ritonavir, telaprevir, amprenavir, atazanavir, delavirdine, fosamprenavir, and saquinavir used to treat HIV infection/AIDS.

• Clarithromycin, erythromycin and telithromycin antibiotics used to treat bacterial infections.

• Voriconazole, itraconazole, ketoconazole, miconazole and posaconazole used to treat fungal infections.

• Nefazodone used to treat depression.

• Boceprevir used to treat hepatitis C infection.

• Conivaptan used to treat low blood sodium levels.

• Mibefradil and diltiazem used to treat high blood pressure and angina.

Simultaneous administration with the above potent isoenzyme CYP3A inhibitor medicines should be avoided.

The following medicines may have increased risk of side effects when given with PALVORED:

• Quinidine generally used to treat heart rhythm problems.

• Colchicine used to treat gout.

• 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 PALVORED:

• Carbamazepine, felbamate, primidone, phenobarbarbital and phenytoin, used to stop seizures or fits.

• Enzalutamide to treat prostate cancer.

• Rifampicin used to treat tuberculosis (TB).

• St. John's Wort, a~~n~~ herbal product used to treat mild depression and anxiety.

• Nevirapine, used to treat HIV infection/AIDS.

• Rifabutin, used to treat bacterial infections.

The concomitant administration with the above potent CYP3A inducer medicines should be avoided.

• Modafinil, used to treat excessive sleepiness.

PALVORED with food, drink and alcohol

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

Pregnancy, Breast-feeding and fertility

You should not use PALVORED if you are pregnant.

You should avoid becoming pregnant while taking PALVORED.

PALVORED may have an adverse effect on the foetus.

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 PALVORED. It is not known if PALVORED is excreted in breast milk.

Fertility

Palbociclib may decrease fertility in men.

Therefore, men may consider sperm preservation before taking PALVORED.

Driving and using machines

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

It is not always possible to predict to what extent PALVORED 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 PALVORED affects you.

PALVORED contains lactose monohydrate and sodium

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.

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

3. HOW TO TAKE PALVORED

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 initial dose is 125 mg of PALVORED taken once a day for 3 weeks followed by 1 week without taking PALVORED. Your doctor will tell you how many capsules of PALVORED to take.

If you experience certain side effects while you are taking PALVORED (see section 4), 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 PALVORED once a day at about the same time every day with food, preferably a meal. Swallow the whole capsule with food. Do not chew or crush the capsules. Do not open the capsules.

If you take more PALVORED than you should

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

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 PALVORED

Do not stop taking PALVORED 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, PALVORED can cause side effects, although not everybody gets them.

Not all side effects reported for PALVORED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PALVORED, please consult your doctor, pharmacist or health care provider for advice or go to the casualty department at your nearest hospital.

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.

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

• 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.

Tell your doctor if you notice any of the following:

Frequent side effects

- infections
- fever with a drop in the white blood cell count (febrile neutropenia)

- decreased appetite
- alteration in taste (dysgeusia)
- blurred vision, increased tearing, dry eye
- nosebleed
- inflammation of the mouth and lips (stomatitis),
- nausea
- vomiting
- diarrhoea
- rash
- hair loss
- dry skin
- feeling of tiredness
- weakness
- fever
- abnormalities in liver blood tests.

Side effects with unknown frequency

- redness, pain, peeling, swelling and blistering of palms of hands and/or soles of feet (Palmar-Plantar Erythrodysaesthesia Syndrome [PPES]).

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the 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 PALVORED.

5. How to store PALVORED

Store at or below 30 °C.

Keep well closed after first opening of the container.

Keep blisters in carton until required for use.

This medicine does not require any special storage conditions.

Do not store in a bathroom.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

Do not use after the expiry date stated on the carton.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What PALVORED contains

The active substance is palbociclib.

Each PALVORED 75 hard gelatin capsule contains 75 mg palbociclib.

Each PALVORED 100 hard gelatin capsule contains 100 mg palbociclib.

Each PALVORED 125 hard gelatin capsule contains 125 mg palbociclib.

The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

The capsule shell ingredients contain gelatin, iron oxide yellow is for 75/ 100/ 125, iron oxide black is for 100/ 125, titanium dioxide, water.

The printing ink contains black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonium solution.

What PALVORED looks like and contents of the pack

PALVORED 75

Pale yellow to yellow granular powder filled in hard gelatin capsules, with light yellow opaque cap and light yellow opaque body, printed with black ink "DRL" on cap and "PLB 75" on body.

PALVORED 100

Pale yellow to yellow granular powder filled in hard gelatin capsules, with gray opaque cap and light yellow opaque body, printed with black ink "DRL" on cap and "PLB 100" on body.

PALVORED 125

Pale yellow to yellow granular powder filled in hard gelatin capsules, with light gray opaque cap and light yellow opaque body, printed with black ink "DRL" on cap and "PLB 125" on body.

PALVORED capsules are packed in bottles of 21 capsules, closed with a child resistant cap and a silica gel sachet inside the bottle.

PALVORED capsules are also packed in cartons of 21 capsules. 3 Blister strips containing 7 tablets each are packed inside the carton.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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This leaflet was last revised in

27 August 2025

Registration numbers

PALVORED 75: 57/26/0520

PALVORED 100: 57/26/0521

PALVORED 125: 57/26/0522

Other sources of information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories web site:

http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100