

PALVORED CAPSULES

Palbociclib (75 mg, 100 mg and 125 mg)

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What Palvored is used for

PALVORED is a prescription medicine used to treat hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic) in combination with:

- an aromatase inhibitor as the first hormonal based therapy in women who have gone through menopause, or
- fulvestrant in women with disease progression following hormonal therapy

How Palvored works

Palvored belongs to the group of medicines called antineoplastics. Palvored interferes with the growth of cancer cells, which are eventually destroyed.

Before you use Palvored

- When you must not use it

It is not known if Palvored is safe and effective in children.

Pregnancy and lactation

Do not take Palvored if you are pregnant, trying to get pregnant or think you may be pregnant.

Palvored can harm your unborn baby. Females who are able to become pregnant and who take Palvored should use effective birth control during treatment, and for at least 2 weeks after stopping Palvored.

Talk to your healthcare provider about birth control methods that may be right for you during this time.

If you become pregnant or think you are pregnant, tell your healthcare provider right away.

It is not known if Palvored passes into your breast milk. Do not take Palvored if you are breast-feeding or plan to breastfeed.

- Before you start to use it

Tell your doctor if you:

- have fever, chills, or any other signs or symptoms of infection.
- have dizziness, shortness of breath, weakness or any increased tendency to bleed and/or to bruise.
- have liver or kidney problems.
- are pregnant, or plan to become pregnant.
- have any other medical conditions.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription medicines, over-the-counter drugs, vitamins, and herbal products.

Some foods and other types of drugs can affect how CYP3A enzymes work. This can change the amount of cancer drug that you absorb. So it changes the dose of cancer drug that your doctor prescribed for you. This can affect how your cancer drug works, making it stronger or weaker.

You should inform your doctor if you are taking medicines containing:

- ketoconazole, itraconazole, voriconazole, posaconazole (used to treat fungal infections);
- clarithromycin, rifampin, telithromycin (used to treat infections);

- ritonavir, lopinavir, indinavir, nelfinavir, saquinavir, telaprevir, efavirenz, etravirine (used to treat viral infections);
- modafinil (used to treat excessive sleepiness);
- bosentan (used to treat high blood pressure in the vessels that carry blood to the lungs);
- verapamil (used to treat hypertension, chest pain, and heart rhythm disorders);
- phenytoin, carbamazepine (used to treat epilepsy and other neurological conditions);
- herbal preparations containing St. John's Wort (*Hypericum perforatum*) (used to treat depression and anxiety);
- cyclosporine, everolimus, sirolimus or tacrolimus (to prevent transplant rejection);
- midazolam (used to help you sleep or for anxiety);
- pimozide (used for treating mental illness);
- alfentanil, fentanyl (used as anaesthetic)
- quinidine (used for treating heart arrhythmia);
- ergotamine, dihydroergotamine (used to treat severe, throbbing headaches).
- nefazodone (used to treat depression)
- nafcillin (used to treat bacterial infections)

How to use Palvored

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Take one capsule of Palvored 125 mg orally once a day for 21 consecutive days, followed by 7 days without Palvored. Your doctor may adjust your dose as needed and tolerated.

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If you have reached menopause, Palvored should be taken with food in combination with recommended dose of an aromatase inhibitor.	discomfort or poisoning. You may need urgent medical attention.	Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.
If you are having disease progression inspite of hormonal therapy, Palvored should be taken in combination with fulvestrant, the recommended dose is 500 mg to be taken on days 1, 15, 29 and once in a month thereafter.	While you are using it - <u>Things you must do</u> Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Palvored.	Palvored may cause serious side effects, including: - Low white blood cell counts (neutropenia). Low white blood cell counts are common when taking Palvored. Your healthcare provider should check your white blood cell counts before and during treatment.
If you have not reached menopause or yet to reach menopause and taking Palvored plus fulvestrant therapy, then you should take luteinizing hormone releasing hormone (LHRH) agonists. - <u>When to use it</u>	Tell your doctor immediately if you become pregnant while taking this medication. Palvored capsules should be swallowed whole with a glass of water. Do not chew, crush or open them prior to swallowing.	If you develop low white blood cell counts during treatment with Palvored, your healthcare provider may stop your treatment, decrease your dose, or may tell you to wait to begin your treatment cycles.
Use as directed by your doctor or pharmacist. You can take the capsule at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.	- <u>Things you must not do</u> Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor.	- Infections. Palvored may cause serious or life-threatening infections. Tell your healthcare provider right away if you develop any signs and symptoms of an infection such as fever or chills.
- <u>How long to use it</u> Continue taking Palvored for as long as your doctor recommends.	Do not give Palvored to anyone else, even if they have the same symptoms or condition as you. Do not take any capsules that have broken open or split.	- Blood clots in the arteries of your lungs (pulmonary embolism or PE). Palvored may cause serious or life-threatening blood clots in the arteries of your lungs. Tell your healthcare provider right away if you have any of the following signs and symptoms of a PE
- <u>If you forget to use it</u> Consult your doctor or pharmacist on what you should do if you forget to use it. If you miss a dose of Palvored or vomit after taking a dose of Palvored, do not take another dose on that day. Take your next dose at your regular time.	Do not consume grapefruit products while on treatment with Palvored.	- shortness of breath - sudden, sharp chest pain that may become worse with deep breathing - rapid heart rate - rapid breathing
- <u>If you use too much (overdose)</u> Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of	- <u>Things to be careful of</u> Driving and using machines This medicine may affect your ability to drive or use machines. If the capsules make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately. Side effects Like all medicines, Palvored can cause side effects, although not everybody gets them.	Other common side effects of PALVORED include: - tiredness - upper respiratory infection - nausea - numbness or tingling in your arms, hands, legs, and feet - sore mouth - unusual hair thinning or hair loss - diarrhea - decreased appetite - vomiting - inflammation inside the mouth - low blood platelet (certain type of white blood cell) count

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- nosebleed
- weakness
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Palvored

- Storage
Store below 30°C
- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
Blister of 21 capsules or 7 capsules

Palvored 125 mg

Pale yellow to yellow granular powder filled in hard gelatin capsules, size “0”, with light grey opaque cap and light yellow opaque body, printed with black ink “DRL” on cap and “PLB 125” on body.

Palvored 100 mg

Pale yellow to yellow granular powder filled in hard gelatin capsules, size “1”, with grey opaque cap and light yellow opaque body, printed with black ink “DRL” on cap and “PLB 100” on body.

Palvored 75 mg

Pale yellow to yellow granular powder filled in hard gelatin capsules, size “2”, with light yellow opaque cap and light yellow opaque body, printed with black ink “DRL” on cap and “PLB 75” on body

- Ingredients

- Active Ingredient
Palbociclib

- Inactive ingredients

Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, and hard gelatin capsule shells.

- MAL number

Palvored 125 mg- MAL22086021AZ
Palvored 100 mg- MAL22086020AZ
Palvored 75 mg- MAL22086019AZ

Manufacturer

Dr. Reddy's Laboratories Limited,
Formulation Unit-VII,
Plot No.PI to P9, Phase-III, VSEZ,
Duvvada, Visakhapatnam District
530046, Andhra Pradesh, India.

Product Registration Holder:

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