



Dr.Reddy's

# Palvored

Palbociclib 75mg, 100mg & 125mg capsules

**Real Evidence**  
**Real Hope**

Dr. Reddy's Palbociclib is approved for use in 9 countries<sup>1</sup>



USA<sup>2</sup>



Malaysia



Jamaica



Chile



Vietnam



India



Brazil



Thailand



Philippines

#### References:

1. Data on file.
2. Tentative approval due to the patent protection till March 5, 2027

#### PALVORED (Palbociclib) Abbreviated Prescribing Information

**Product name and strength of the active ingredient:** Each PALVORED Capsule contains: Palbociclib 75 mg, 100 mg, 125 mg Source of Capsules: Bovine. Indications: PALVORED is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: i) an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women, or; ii) fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist. **Recommended Dose & Administration:** The recommended dose of PALVORED is a 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days. PALVORED should be taken with food, preferably a meal. The capsules should be swallowed whole (should not be chewed, crushed, or opened prior to swallowing). No capsule should be ingested if it is broken, cracked, or otherwise not intact. **Dose Modification:** PALVORED dose modifications for hematologic and non-hematologic toxicities are based on toxicity grade, with specific guidelines for monitoring and adjusting treatment. Dose Modifications for Strong CYP3A Inhibitors: Avoid using strong CYP3A inhibitors with PALVORED. If necessary, reduce the PALVORED dose to 75 mg once daily. Resume the original dose after discontinuing the inhibitor. Dose Modifications for Hepatic Impairment: No dose adjustment is needed for mild or moderate hepatic impairment. For severe hepatic impairment, the recommended dose is 75 mg once daily for 21 days, followed by 7 days off treatment in a 28-day cycle. **Contraindications:** PALVORED is contraindicated in cases of hypersensitivity to the active substance or excipients, and with the use of St. John's Wort preparations. **Special warnings and precautions for use:** Pre/perimenopausal women: Ovarian ablation/suppression with LHRH agonist mandatory with aromatase inhibitors. Palbociclib with fulvestrant studied only with LHRH agonist. Critical visceral disease: Efficacy and safety not studied. Haematological disorders: Dose interruption/reduction/delay recommended for Grade 3/4 neutropenia. Monitor appropriately. Interstitial lung disease (ILD)/pneumonitis: Can be severe/fatal. Monitor for symptoms. Interrupt PALVORED if suspected, discontinue if severe. Infections: Higher risk due to myelosuppression. Monitor and treat promptly. Inform patients to report fever. Hepatic/Renal impairment: Administer with caution in moderate/severe cases. Monitor for toxicity. CYP3A4 interactions: Avoid strong inhibitors. If unavoidable, reduce PALVORED dose to 75 mg daily. Avoid strong inducers. Contraception: Highly effective method required for women of childbearing potential and their partners. Lactose: Contains lactose. Not for patients with galactose intolerance, lactase deficiency, or glucose-galactose malabsorption. **Pregnancy and Lactation:** PALVORED is not recommended during pregnancy and in women of childbearing potential not using contraception. Patients receiving PALVORED should not breast feed. **Undesirable effects:** The most common adverse reactions of any grade reported in patients receiving palbociclib were neutropenia, infections, leukopenia, fatigue, nausea, stomatitis, anaemia, diarrhoea, alopecia and thrombocytopenia. The most common Grade 3 adverse reactions of palbociclib were neutropenia, leukopenia, infections, anaemia, aspartate aminotransferase (AST) increased, fatigue, and alanine aminotransferase (ALT) increased. **Storage Condition:** Store below 30°C. **Dosage forms and packaging available:** Blister of 7's Capsules. Such 1 or 3 blisters are packed into an outer carton with a pack insert. **Full prescribing information is available upon request. Please consult the full prescribing information before prescribing**

Dr.Reddy's

Dr. Reddy's Laboratories Malaysia Sdn. Bhd. (1238154-X)  
Unit No. SO-29-7 & SO-29-8, Menara 1, Strata Office, No.3, Jalan Bangsar,  
KL Eco City, 59200 Kuala Lumpur. Tel: +603 8679 1002 Email: info.mys@drreddys.com

For Healthcare Professionals Only

R1316052-MY-CO-10122024-0270