PALBOBREST® (PALBOCICLIB) CAPSULE

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PALBOCICLIB

PALBOBREST®(PALBOCICLIB) CAPSULE FOR ORAL USE
Read this patient information carefully before you start taking PALBOBREST® because it answers some common questions about PALBOBREST®. This medication is prescribed for your current condition, therefore do not use it, in similar cases and do not recommend it to others.
To report SUSPECTED ADVERSE REACTIONS, contact Noavaran Daroui Kimia Co.
at +982188012946 or send email to medical@kimia-pharma.co

Read this patient information carefully before you start taking PALBOBREST® because it contains important information for you. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment.

COMPOSITION

Each capsule contains 125 mg Palbociclib.

Mechanism of action

Palbobrest® is a highly selective inhibitor of cyclin-dependent kinases 4 and 6, which leads to disruption of cancer cell proliferation.

Pharmacokinetic

Absorption
Bioavailability: 46%, Peak plasma time: 4-12 hr, Steady-state achieved: 8 days.
Distribution
Protein bound: 85%, No concentration dependence over the concentration range of 500 ng/mL to 5000 ng/mL.
Metabolism
Extensively metabolized, primarily by CYP3A and SULT2A1
Excretion
Half-life: 29 hr. (patients with advanced breast cancer), Excretion: 74.1% feces (2.3% unchanged); 17.5% urine (6.9% unchanged). Majority of the dose eliminated in feces was metabolites.

INDICATION

Palbobrest® is a kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:

- An aromatase inhibitor women or in men; or
- Fulvestrant in patients with disease progression following endocrine therapy.

Dosage and administration

Palbobrest® capsules are taken orally with food in combination with an aromatase inhibitor or fulvestrant.

- Recommended starting dose: 125 mg once daily taken with food for 21 days followed by 7 days off treatment.
- Dosing interruption and/or dose reductions are recommended based on individual safety and tolerability.

The safety and efficacy of Palbobrest® in pediatric patients have not been studied.

Side effects / Adverse reactions

The most common side effects in people who take Palbobrest® include:

- **Low white blood cell counts (neutropenia).** Low white blood cell counts are very common when taking Palbobrest® and may cause serious infections that can lead to death. Your healthcare provider should check your white blood cell counts before and during treatment. If you develop low white blood cell counts during treatment with Palbobrest®, your healthcare provider may stop your treatment, decrease your dose, or may tell you to wait to begin your treatment cycle. Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.
- **Lung problems (pneumonitis).** Palbobrest® 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:
  - trouble breathing or shortness of breath
  - cough with or without mucus
  - chest pain

Common side effects of Palbobrest® when used with either letrozole or fulvestrant include: low red blood cell counts and low platelet are common with Palbobrest®.
Call your healthcare provider right away if you develop any of these symptoms during treatment: dizziness, shortness of breath, weakness, bleeding or bruising more easily, nosebleeds.
Infections, tiredness, nausea, sore mouth, abnormalities in liver blood tests, diarrhea, hair thinning or hair loss, vomiting, rash, loss of appetite.
Palbobrest® may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider about family planning options before starting Palbobrest® if this is a concern for you.
These are not all the possible side effects of Palbobrest®. Call your doctor for medical advice about side effects.

Drug interaction

- Agents That May Increase Palbobrest® Plasma Concentrations: Avoid concomitant use of strong CYP3A inhibitors (e.g., clarithromycin, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, verapamil, and voriconazole).
- Avoid Grapefruit or grapefruit juice during Palbobrest® treatment. If coadministration of Palbobrest® a strong CYP3A inhibitor cannot be avoided, reduce the dose of Palbobrest®.
- Agents that may decreased Palbobrest® Plasma Concentrations: Avoid concomitant use of strong CYP3A inducers (e.g., phenytoin, rifampin, carbamazepine and St John's Wort) and moderate CYP3A inducers (e.g., bosentan, efavirenz, etravirine, modafinil, and nafcillin).
- Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking Palbobrest® with certain other medicines may affect how Palbobrest® works and can cause side effects.

Warnings

Before taking Palbobrest®, tell your healthcare provider about all of your medical conditions, including if you:

- Have fever, chills, or any other signs or symptoms of infection.
- Have liver or kidney problems.
- Have any other medical conditions.
- Are pregnant, or plan to become pregnant. If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- Are breastfeeding or plan to breastfeed.

Missed dose

If you miss a dose of Palbobrest® or vomit after taking a dose of Palbobrest®, do not take another dose on that day. Take your next dose at your regular time.

OVERDOSE

If you take too much Palbobrest® (overdose on Palbobrest®) call your healthcare provider or go to the nearest hospital emergency room right away.

Pregnancy and lactation

- Based on findings in animals and mechanism of action, Palbobrest® can cause fetal harm when administered to a pregnant woman. If you are able to become pregnant, your healthcare provider will do a pregnancy test before starting treatment with Palbobrest®.
- Females who are able to become pregnant should use effective birth control during treatment and for at least 3 weeks after the last dose of Palbobrest®.
- Males with female partners who can become pregnant should use effective birth control during treatment with Palbobrest® for at least 3 months after the last dose of Palbobrest®.
- It is not known if Palbobrest® passes into your breast milk. Do not breastfeed during treatment with Palbobrest® and for 3 weeks after the last dose.

Patient information

- Take Palbobrest® exactly as your healthcare provider tells you.
- Take Palbobrest® with food.
- Palbobrest® should be taken at about the same time each day.
- Swallow Palbobrest® capsules whole. Do not chew, crush or open Palbobrest® capsules before swallowing them.
- Do not take any Palbobrest® capsules that are broken, cracked, or that look damaged.
- Avoid grapefruit and grapefruit products during treatment with Palbobrest®. Grapefruit may increase the amount of Palbobrest® in your blood.
- Do not change your dose or stop taking Palbobrest® unless your healthcare provider tells you.

Storage

- Store Palbobrest® capsules below 30°C.
- Keep Palbobrest® capsules in the original container with the lid tightly closed.
- Keep Palbobrest® and all medicines out of the reach of children.

Packaging

Bottle of 21 Capsules

References
http://labeling.pfizer.com/ShowLabeling.aspx?id=2191#section-17
https://bnf.nice.org.uk/drug/palbociclib.html#patientAndCarerAdvice

Manufactured By
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