Description

Palbace: Palbociclib 100 Mg Capsules

Brand Name : Palbace Composition : Palbociclib

Manufactured by: Pfizer Pharmaceuticals, Inc.

Strength: 100 mg Form: Capsules

Packing: Pack of 21 Capsules

What is Palbociclib?

Palbociclib is a <u>cancer</u> medicine that interferes with the growth and spread of cancer cells in the body.

Palbociclib is used in men and women to treat certain types of advanced <u>breast</u> <u>cancer</u> that has spread to other parts of the body.

In postmenopausal women, palbociclib is given in combination with a hormonal medicine called <u>letrozole(Femara)</u>. In others, palbociclib is given together with fulvestrant (Faslodex).

Palbociclib may also be used for purposes not listed in this medication guide.

Important Information

Follow all directions on your medicine label and package. Tell each of your healthcare providers about all your medical conditions, <u>allergies</u>, and all medicines you use.

Before taking this medicine

You should not use palbociclib if you are allergic to it.

To make sure palbociclib is safe for you, tell your doctor if you have:

- liver disease; or
- kidney disease.

Do not use palbociclib if you are pregnant. It could harm the unborn baby. Use effective <u>birth control</u>to prevent pregnancy while you are using this medicine and for at least 3 weeks after your last dose.

You may need to have a negative pregnancy test before starting this treatment.

It is not known whether palbociclib passes into breast milk or if it could harm a nursing baby. You should not breast-feed while using this medicine.

How should I take palbociclib?

Follow all directions on your prescription label. Your doctor may occasionally change your dose to make sure you get the best results. Do not use this medicine in larger or smaller amounts or for longer than recommended.

Palbociclib is given in a 28-day treatment cycle, and you may only need to take the medicine during the first 3 weeks of each cycle. Your doctor will determine how long to treat you with palbociclib.

Take with food.

Take the medicine at the same time each day.

Do not crush, chew, break, or open a palbociclib capsule. Swallow it whole.

If you vomit after taking the medicine, wait until the next day to take your next dose.

Do not use a broken or damaged pill.

Palbociclib can lower blood cells that help your body fight infections and help your blood to clot. This can make it easier for you to bleed from an injury or get sick from being around others who are ill. Your blood may need to be tested often.

Store at room temperature away from moisture and heat.

What happens if I miss a dose?

Skip the missed dose and do not take the medicine again until your next scheduled dose. Do not take extra medicine to make up the missed dose.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking palbociclib?

<u>Grapefruit</u> and <u>grapefruit juice</u> may interact with palbociclib and lead to unwanted side effects. Avoid the use of grapefruit products while taking palbociclib.

Avoid being near people who are sick or have infections. Tell your doctor at once if you develop signs of infection.

Palbociclib side effects

Get emergency medical help if you have **signs of an allergic reaction**: <u>hives</u>; difficult breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have:

- easy bruising, unusual bleeding (nose, mouth, vagina, or rectum), purple
 or red pinpoint spots under your skin;
- blisters or ulcers in your mouth, red or swollen gums, trouble swallowing;
- low white blood cell counts—<u>fever</u>, swollen gums, painful mouth sores, pain when swallowing, skin sores, cold or flu symptoms, cough, trouble breathing:
- low red blood cells (anemia)—pale skin, feeling light-headed or short of breath, rapid heart rate, trouble concentrating; or
- signs of a blood clot in the lung-chest pain, sudden cough, wheezing,
 rapid breathing, coughing up blood.

Your cancer treatments may be delayed or permanently discontinued if you have certain side effects.

Common side effects may include:

- <u>nausea</u>, <u>vomiting</u>, <u>diarrhea</u>, loss of appetite;
- mouth sores, decreased sense of taste;
- weakness, feeling tired;
- numbness, tingling, or burning pain in your arms, legs, hands or feet;
- abnormal liver function tests;
- cold symptoms such as stuffy nose, sneezing, sore throat;
- nosebleed; or
- dry skin, temporary hair loss.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Palbociclib dosing information

Usual Adult Dose for Breast Cancer:

28-day cycle: 125 mg orally once a day for 21 consecutive days followed by 7 days off treatment

Comments: Take with food in combination with letrozole 2.5 mg orally once a day throughout the 28-day cycle.

Use: In combination with letrozole for the treatment of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy

What other drugs will affect palbociclib?

Other drugs may interact with palbociclib, including prescription and over-the-counter medicines, <u>vitamins</u>, and <u>herbal products</u>. Tell each of your health care providers about all medicines you use now and any medicine you start or stop using.

Palbociclib is an oral chemotherapy used to treat advanced breast cancer. This drug is used as part of a combination therapy. That means it is taken with other drugs. Palbociclib is generally taken in combination with letrozole

Palbace (Palbociclip 125mg)) is a product of Pfizer and is known as IBRANCE in other parts of the world

The drug was reviewed and approved under the <u>Food and Drug Administration</u>'s (FDA) accelerated <u>Priority Review</u> and <u>Breakthrough Therapy</u> designation programs on February of 2015

The drug was approved for use in the European Union in November 2016 as a treatment for hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer

Palbace comes in capsule form in 125 mg dose. 1 pack has 21 capsules.