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Source : U.S. National Library of Medicine

URL of this page: <https://medlineplus.gov/druginfo/meds/a615013.html>

Palbociclib

pronounced as (pal" boe sye' klib)

Notice:

[Posted 09/13/2019]

AUDIENCE: Patient, Health Professional, Oncology

ISSUE: FDA is warning that palbociclib (Ibrance[®]), ribociclib (Kisqali[®]), and abemaciclib (Verzenio[®]) used to treat some patients with advanced breast cancers may cause rare but severe inflammation of the lungs. FDA has approved new warnings about this risk to the prescribing information and Patient Package Insert for the entire class of these cyclin-dependent kinase 4/6 (CDK 4/6) inhibitor medicines. The overall benefit of CDK 4/6 inhibitors is still greater than the risks when used as prescribed.

BACKGROUND: CDK 4/6 inhibitors are a class of prescription medicines that are used in combination with hormone therapies to treat adults with hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative advanced or metastatic breast cancer that has spread to other parts of the body. CDK 4/6 inhibitors block certain molecules involved in promoting the growth of cancer cells. FDA approved palbociclib in 2015, and both ribociclib and abemaciclib in 2017. CDK 4/6 inhibitors have been shown to improve the amount of time after the start of treatment the cancer does not grow substantially and the patient is alive, called progression-free survival (See List of FDA-Approved CDK 4/6 Inhibitors below).

RECOMMENDATION: *Patients* should notify your health care professional right away if you have any new or worsening symptoms involving your lungs, as they may indicate a rare but life-threatening condition that can lead to death. Symptoms to watch for include:

- Difficulty or discomfort with breathing
- Shortness of breath while at rest or with low activity

Do not stop taking your medicine without first talking to your health care professional. All medicines have side effects even when used correctly as prescribed, but in general the benefits of taking these medicines outweigh these risks. It is important to know that people respond differently to all medicines depending on their health, the diseases they have, genetic factors, other medicines they

are taking, and many other factors. Specific risk factors to determine how likely it is that a particular person will experience severe lung inflammation when taking palbociclib, ribociclib, or abemaciclib have not been identified.

Health care professionals should monitor patients regularly for pulmonary symptoms indicative of interstitial lung disease (ILD) and/or pneumonitis. Signs and symptoms may include:

- hypoxia
- cough
- dyspnea
- interstitial infiltrates on radiologic exams in patients in whom infectious, neoplastic, and other causes have been excluded.

Interrupt CDK 4/6 inhibitor treatment in patients who have new or worsening respiratory symptoms, and permanently discontinue treatment in patients with severe ILD and/or pneumonitis.

For more information visit the FDA website at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation>

[<http://www.fda.gov/Safety/MedWatch/SafetyInformation>] and <http://www.fda.gov/Drugs/DrugSafety>

[<http://www.fda.gov/Drugs/DrugSafety>] .

Why is this medication prescribed?

Palbociclib is used in combination with anastrozole (Arimidex), exemestane (Aromasin), or letrozole (Femara) to treat a certain type of hormone receptor–positive, advanced breast cancer (breast cancer that depends on hormones such as estrogen to grow) or breast cancer that has spread to other parts of the body in women who have experienced menopause (change of life; end of monthly menstrual periods) or in men. Palbociclib is also used along with fulvestrant (Faslodex) to treat a certain type of hormone receptor–positive, advanced breast cancer (breast cancer that depends on hormones such as estrogen to grow) or breast cancer that has spread to other parts of the body in people who have been treated with an antiestrogen medication such as tamoxifen (Nolvadex). Palbociclib is in a class of medications called kinase inhibitors. It works by blocking the action of the abnormal protein that signals cancer cells to multiply. This helps stop or slow the spread of cancer cells.

How should this medicine be used?

Palbociclib comes as a capsule to take by mouth. It is usually taken with food once daily for the first 21 days of a 28-day cycle. Your doctor will decide how many times you should repeat this cycle. Take palbociclib at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take palbociclib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole; do not open, chew, or crush them. Do not take capsules that are broken or cracked.

If you vomit after taking palbociclib, do not take another dose. Continue your regular dosing schedule.

Your doctor may decrease your dose or temporarily or permanently stop your treatment if you experience certain side effects. Be sure to tell your doctor how you are feeling during your treatment with palbociclib.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking palbociclib,

- tell your doctor and pharmacist if you are allergic to palbociclib, any other medications, or any of the ingredients in palbociclib capsules. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: antifungals such as itraconazole (Onmel, Sporanox, Tolsura), ketoconazole, posaconazole (Noxafil), and voriconazole (Vfend); certain medications to treat seizures such as carbamazepine (Carbatrol, Equetro, Epitol, Tegretol, others) and phenytoin (Dilantin, Phenytek); clarithromycin; enzalutamide (Xtandi); ergot alkaloids such as dihydroergotamine (D.H.E 45, Migranal) and ergotamine (Ergomar, in Cafergot, in Migergot); certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) including indinavir (Crixivan), lopinavir (in Kaletra), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra, in Viekira Pak), saquinavir (Invirase), and telaprevir (no longer available in the U.S.); fentanyl (Abstral, Fentora, Lazanda, Subsys, others); immunosuppressants such as cyclosporine (Gengraf, Neoral, Sandimmune), everolimus (Afinitor, Zortress), sirolimus (Rapamune), and tacrolimus (Astagraf XL, Envarsus XR, Prograf); midazolam; nefazodone; pimozone (Orap); quinidine (in Nuedexta); rifampin (Rimactane, Rifadin, in Rifater, in Rifamate); and telithromycin (Ketek). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with palbociclib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor and pharmacist what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have an infection or if you have or have ever had liver or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or if you plan on fathering a child. If you are female, you will need to take a pregnancy test before you start treatment and use birth control to prevent pregnancy during your treatment and for at least 3 weeks after your final dose. If you are a male, you and your partner should use birth control during your treatment with palbociclib and for 3 months after your final dose. Talk to your doctor about birth control methods that you can use during your treatment. If you or your partner become pregnant while taking palbociclib, call your doctor immediately. Palbociclib may harm the fetus.
- tell your doctor if you are breastfeeding. You should not breastfeed while you are taking palbociclib and for 3 weeks after the final dose.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking palbociclib.

- you should know that this medication may decrease fertility in men. Talk to your doctor about the risks of taking palbociclib.

What special dietary instructions should I follow?

Do not eat grapefruit or drink grapefruit juice while taking this medication.

What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not take a double dose on the same day to make up for a missed one.

What side effects can this medication cause?

Palbociclib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- diarrhea
- vomiting
- decreased appetite
- changes in taste
- tiredness
- numbness or tingling in your arms, hands, legs, and feet
- sores on the lips, mouth, or throat
- unusual hair thinning or hair loss
- dry skin
- rash

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- fever, chills, or signs of infection
- shortness of breath
- dizziness
- fast, irregular, or pounding heartbeat
- weakness
- unusual bleeding or bruising
- nosebleeds

Palbociclib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests before and during your treatment to check your body's response to palbociclib.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Ibrance®

Last Revised - 06/15/2019

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Page last updated: 25 March 2022