

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrIBRANCE®

Palbociclib Tablets

Read this carefully before you start taking **IBRANCE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **IBRANCE**.

Your breast cancer will be treated with **IBRANCE** in combination with another family of medications, called aromatase inhibitors or with fulvestrant. Read the Patient Medication Information leaflet for the other medication carefully as well as this one.

Serious Warnings and Precautions

Take IBRANCE under the care of a healthcare professional who knows how to use anti-cancer drugs.

IBRANCE can cause the following serious side effect:

- **Neutropenia:** abnormally low number of white blood cells in your blood.

What is IBRANCE used for?

IBRANCE is a prescription medicine. It is used in pre/peri-menopausal or post-menopausal women, and men, to treat hormone receptor positive breast cancer that has spread to other parts of the body. It is used with:

- aromatase inhibitors
- fulvestrant: to treat patients whose breast cancer has failed other hormone treatments.

Pre or peri-menopausal women (women who have not gone through menopause) and men treated with a combination of IBRANCE and aromatase inhibitors and pre/perimenopausal women treated with a combination of IBRANCE and fulvestrant should also be treated with a medicine that lowers the amount of sex hormones made by the body luteinizing hormone releasing hormone (LHRH) agonist).

How does IBRANCE work?

Palbociclib belongs to a family of medications called kinase inhibitors. These medications work by stopping cancer cells from dividing and growing. When given together with an aromatase inhibitor or fulvestrant, IBRANCE may slow down the growth and spread of breast cancer cells.

What are the ingredients in IBRANCE?

Medicinal ingredients: Palbociclib

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, FD&C Blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide (in 75 mg and 125 mg tablets), succinic acid, titanium dioxide, triacetin and yellow iron oxide (in 100 mg tablet).

IBRANCE comes in the following dosage forms:

Tablets: 75 mg, 100 mg, 125 mg

Risk of medication error: Be sure to follow the directions on how to take IBRANCE tablets. These can be taken with or without food.

Do not use IBRANCE if:

- you are allergic to palbociclib or any of the other ingredients of IBRANCE (see [What are the ingredients in IBRANCE?](#)).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take IBRANCE. Talk about any health conditions or problems you may have, including if you:

- have fever, chills, or any other signs or symptoms of infection
- have heart problems, including a condition called long QT syndrome
- have liver or kidney problems
- have any other medical conditions

Other warnings you should know about:

IBRANCE may cause:

- **Serious or life-threatening infections.** Your healthcare professional will decide when to perform blood tests and will interpret the results.
- **Neutropenia and Leukopenia (low white blood cells).**
- **Anemia (low red blood cells).**
- **Lung problems (pneumonitis):** severe or life-threatening inflammation of the lungs during treatment that can lead to death.
- **Blood clots (venous thromboembolism):** in the lungs, arms or legs.

See the [Serious side effects and what to do about them](#) table, below, for more information on these and other serious side effects.

Pregnancy, Breastfeeding and Fertility:**Women:**

- IBRANCE should only be used in women who are postmenopausal or women who have not gone through menopause when used with a medicine to stop their ovaries from making estrogen.
- IBRANCE should not be taken during pregnancy. Talk to your healthcare professional if you are pregnant, think you might be pregnant or plan to become pregnant. IBRANCE may harm your unborn baby.
- If you are able to become pregnant and are taking IBRANCE, you should use effective birth control during treatment and for at least 21 days after the final dose. Talk to your healthcare professional about the birth control options that may be right for you.
- Talk to your healthcare professional if you are breastfeeding or planning to breastfeed. It is not known if IBRANCE passes into breast milk. You and your healthcare professional should decide if you will take IBRANCE or breastfeed. You should not do both.

Men:

- If you are a male patient with a female partner who is able to become pregnant, you should use effective birth control during treatment with IBRANCE and for at least 97 days after the final dose.
- IBRANCE may affect fertility in men. Male patients should talk to their healthcare professional about sperm preservation before they start therapy with IBRANCE.

Children and adolescents (under 18 years of age): IBRANCE should not be used in children and adolescents under 18 years of age.

Driving and using machines: Fatigue and dizziness can occur with IBRANCE. Give yourself time after taking IBRANCE to see how you feel before driving or using machinery.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with IBRANCE:

- medicines for bacterial infections (antibiotics), such as clarithromycin, nafcillin, rifampin and telithromycin
- medicines for fungal infections, such as ketoconazole, itraconazole, posaconazole and voriconazole
- some medicines for high blood pressure, such as bosentan
- HIV medicines, such as saquinavir, ritonavir, indinavir, nelfinavir, lopinavir, efavirenz and etravirine
- antiviral medicines, such as telaprevir
- antidepressant medicines, such as nefazodone
- medicines to treat epilepsy, such as carbamazepine and phenytoin
- medicines to treat certain types of sleep disorders, such as modafinil
- St. John's wort, an herbal medicine used to treat depression
- medicines to treat high cholesterol (statins), such as rosuvastatin, atorvastatin, simvastatin, and lovastatin.
- grapefruit. Do not drink grapefruit juice or eat grapefruit, or products containing grapefruit extracts, star fruit, pomegranate, Seville oranges or other similar fruits. They may change the amount of IBRANCE in your body.

Other medicines not listed here may also interact with IBRANCE

How to take IBRANCE Tablets:

Always take IBRANCE tablets exactly as your healthcare professional tells you. Your healthcare professional might adjust your dose if you have certain side effects. Do not change your dose or stop IBRANCE unless told to do so by your healthcare professional. Check with your healthcare professional if you are not sure.

- **Take with or without food** once a day for 21 days. This is followed by 7 days off (3 weeks on, 1 week off) for a 28 day cycle.
- Swallow whole. Do NOT chew, crush or split the tablets. Do NOT take tablets if they are broken,

cracked or look damaged.

- Take your dose of IBRANCE at approximately the same time each day.
- If you vomit after taking a dose of IBRANCE, do not take an extra dose. Take your next dose at your regular time.

Usual Adult dose:

Recommended starting dose: 125 mg

Tablet: 1 tablet once a day with or without food for 21 days followed by 7 days with no IBRANCE treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much IBRANCE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss a day's dose, do not take an extra dose the next day. Take your next dose at your regular time.

What are possible side effects from using IBRANCE?

These are not all the possible side effects you may have when taking IBRANCE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- shortness of breath
- tiredness or weakness
- cough
- mouth sores
- unusual hair thinning or loss
- nausea, vomiting
- bruising
- loss of appetite
- tingling or abnormal feeling (especially in arms and legs)
- nose bleed
- headache
- constipation
- rash

IBRANCE can cause abnormal blood test results. Your healthcare professional will do blood tests before, during and after your treatment. These will tell your healthcare professional how IBRANCE is affecting your blood.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Anemia (low level of red blood cells): fatigue, loss of energy, weakness, shortness of breath		√	
Infections: fever, chills, dizziness, weakness, shortness of breath		√	
Neutropenia and Leukopenia (low level of white blood cells): infection, fever		√	
COMMON			
Diarrhea	√		
Fever		√	
Palmar-plantar erythrodysesthesia syndrome (also called Hand-Foot syndrome): red or swollen palms, thick calluses and blisters of the hands and soles of the feet, tingling or burning, tightness of the skin		√	
Thrombocytopenia (low level of blood platelets): increased tendency to bruise or bleed		√	
Venous thromboembolism (blood clots): <ul style="list-style-type: none"> • Pulmonary embolism (lung): chest pain that may increase with deep breathing, cough, coughing up bloody sputum, shortness of breath • Deep vein thrombosis (arm or leg): swelling, pain, arm or leg may be warm to the touch and may appear red 			√
RARE			
Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the center; possibly swollen lips, mild itching or burning skin, fever		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Lung problems (pneumonitis): trouble breathing or shortness of breath, cough with or without mucus, chest pain		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at 15°C to 30°C in the original blister pack to protect from moisture.
- Keep out of reach and sight of children.

If you want more information about IBRANCE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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