

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrIBRANCE[®] **Palbociclib Capsules**

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 doctor who knows how to use anti-cancer drugs.

- **IBRANCE** may cause the number of white blood cells in your blood to be abnormally low.

What is **IBRANCE used for?**

IBRANCE is a prescription medicine. It is used to treat breast cancer that has spread to other parts of the body. It is used with:

- aromatase inhibitors
 - in women after menopause or in men to treat estrogen receptor positive breast cancer.
- fulvestrant
 - to treat hormone receptor positive breast cancer that have failed with other hormone treatments. Women who have not gone through menopause need to use **IBRANCE** with a medicine to shutdown their ovaries.

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 Capsules?**

Medicinal ingredients: Palbociclib

Non-medicinal ingredients: ammonium hydroxide, colloidal silicon dioxide, gelatin, lactose monohydrate, magnesium stearate, microcrystalline cellulose, propylene glycol, red iron oxide, shellac, simethicone, sodium starch glycolate, titanium dioxide, and yellow iron oxide.

IBRANCE comes in the following dosage forms:

Capsules: 75 mg, 100 mg and 125 mg

PLEASE NOTE: IBRANCE is also available as **tablets**.

Risk of medication error: Be sure to follow the directions on how to take IBRANCE capsules. These must be taken with food.

Do not use IBRANCE if:

You are allergic to palbociclib or any of the other ingredients of 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.
- Are pregnant, or plan to become pregnant. IBRANCE may harm your unborn baby.
- Are a woman who is able to become pregnant. IBRANCE is recommended for use only 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. If you are able to become pregnant and are taking IBRANCE, you should use birth control during treatment and for at least 21 days after stopping IBRANCE. Talk to your doctor about the birth control methods that may be right for you. If you become pregnant, tell your doctor right away.
- Are a man with a female partner who is able to become pregnant. If so, you should use effective birth control during treatment with IBRANCE and up to 97 days after the final dose of IBRANCE.
- Male patients should consider sperm preservation prior to beginning therapy with IBRANCE.
- Are breastfeeding or plan to breastfeed. It is not known if IBRANCE passes into breast milk. You and your doctor should decide if you will take IBRANCE or breastfeed. You should not do both.

Other warnings you should know about:

IBRANCE may cause:

- **Serious or life-threatening infections.** Your doctor will decide when to perform blood tests and will interpret the results. Tell your doctor right away if you have fever, chills, or any other signs or symptoms of infection.
- **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. 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, or chest pain.

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. Be careful when driving or operating machinery while you are taking IBRANCE.

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

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

The following may interact with IBRANCE:

- Medicines for 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
- 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 drugs not listed here may also interact with IBRANCE

How to take IBRANCE Capsules:

Always take IBRANCE capsules exactly as your healthcare professional tells you. Check with your healthcare professional if you are not sure.

Be sure the pharmacist has provided **capsules** for you. The directions on how to take IBRANCE are different for capsules and tablets.

- **Take with 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 open the capsules. Do NOT take capsules 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.

Recommended starting dose: 125 mg

Usual Adult dose:

Capsule: 1 capsule once a day with food for 21 days followed by 7 days with no IBRANCE treatment.

Your doctor may interrupt, delay or reduce your dose. This may happen if you have certain side effects while taking IBRANCE.

Overdose:

If you think you have taken too much IBRANCE contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no 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 feel when taking IBRANCE. If you experience any of these side effects or side effects not listed here, contact your healthcare professional. Please also see the Serious Warnings and Precautions Box.

Side effects may include:

- Decrease in the number of white blood cell, red blood cell and platelet counts in the bloodstream
- 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
- Diarrhea
- Constipation
- Rash

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		√	
Neutropenia and Leukopenia (low level of white blood cells): infection, fever		√	
Infections: , fever, chills, dizziness, weakness, shortness of breath		√	
COMMON			
Thrombocytopenia (low level of blood platelets): Increased tendency to bruise or bleed		√	
Diarrhea	√		
Fever		√	
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, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
--

Storage:

Capsules: Store at 15°C to 30°C.

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.html) (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

Last Revised 29 November 2019

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

P^rIBRANCE[®] **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 doctor who knows how to use anti-cancer drugs.

- **IBRANCE** may cause the number of white blood cells in your blood to be abnormally low.

What is **IBRANCE used for?**

IBRANCE is a prescription medicine. It is used to treat breast cancer that has spread to other parts of the body. It is used with:

- aromatase inhibitors
 - in women after menopause or in men to treat estrogen receptor positive breast cancer.
- fulvestrant
 - to treat hormone receptor positive breast cancer that have failed with other hormone treatments. Women who have not gone through menopause need to use **IBRANCE** with a medicine to shutdown their ovaries.

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 Tablets?**

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

PLEASE NOTE: IBRANCE is also available as **capsules**.

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.

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.
- Are pregnant, or plan to become pregnant. IBRANCE may harm your unborn baby.
- Are a woman who is able to become pregnant. IBRANCE is recommended for use only 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. If you are able to become pregnant and are taking IBRANCE, you should use birth control during treatment and for at least 21 days after stopping IBRANCE. Talk to your doctor about the birth control methods that may be right for you. If you become pregnant, tell your doctor right away.
- Are a man with a female partner who is able to become pregnant. If so, you should use effective birth control during treatment with IBRANCE and up to 97 days after the final dose of IBRANCE.
- Male patients should consider sperm preservation prior to beginning therapy with IBRANCE.
- Are breastfeeding or plan to breastfeed. It is not known if IBRANCE passes into breast milk. You and your doctor should decide if you will take IBRANCE or breastfeed. You should not do both.

Other warnings you should know about:

IBRANCE may cause:

- **Serious or life-threatening infections.** Your doctor will decide when to perform blood tests and will interpret the results. Tell your doctor right away if you have fever, chills, or any other signs or symptoms of infection.
- **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. 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, or chest pain.

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. Be careful when driving or operating machinery while you are taking IBRANCE.

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

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

The following may interact with IBRANCE:

- Medicines for 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
- 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 drugs not listed here may also interact with IBRANCE

How to take IBRANCE Tablets:

Always take IBRANCE tablets exactly as your healthcare professional tells you. Check with your healthcare professional if you are not sure.

Be sure the pharmacist has provided **tablets** for you. The directions on how to take IBRANCE are different for tablets and capsules.

- **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.

Recommended starting dose: 125 mg

Usual Adult dose:

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

Your doctor may interrupt, delay or reduce your dose. This may happen if you have certain side effects while taking IBRANCE.

Overdose:

If you think you have taken too much IBRANCE contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no 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 feel when taking IBRANCE. If you experience any of these side effects or side effects not listed here, contact your healthcare professional. Please also see the Serious Warnings and Precautions Box.

Side effects may include:

- Decrease in the number of white blood cell, red blood cell and platelet counts in the bloodstream
- 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
- Diarrhea
- Constipation
- Rash

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		√	
Neutropenia and Leukopenia (low level of white blood cells): infection, fever		√	
Infections: fever, chills, dizziness, weakness, shortness of breath		√	
COMMON			
Thrombocytopenia (low level of blood platelets): Increased tendency to bruise or bleed		√	
Diarrhea	√		
Fever		√	
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, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
--

Storage:

Tablets: 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.html) (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

Last Revised 24 January 2020