

IBRANCE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using IBRANCE?

IBRANCE contains the active ingredient palbociclib. IBRANCE is used to treat advanced breast cancer.

For more information, see Section [1. Why am I using IBRANCE?](#) in the full CMI.

2. What should I know before I use IBRANCE?

Do not use if you have ever had an allergic reaction to palbociclib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use IBRANCE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines and IBRANCE may interfere with each other. It is important you tell your doctor or pharmacist if you are taking any medicines used to treat fungal or bacterial infections, HIV/AIDS infections, hepatitis C, tuberculosis, certain heart conditions or high blood pressure, epilepsy/seizures and depression and sleep disorders.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use IBRANCE?

- IBRANCE is a tablet and is taken by mouth.
- Your doctor will advise how much IBRANCE to use depending on your medical condition.
- Detailed instructions on how to take IBRANCE are provided in the 'Instructions for Use' leaflet inside the pack.

More instructions can be found in Section [4. How do I use IBRANCE?](#) in the full CMI.

5. What should I know while using IBRANCE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, pharmacist or dentist
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	<p>you visit that you are using IBRANCE.</p> <ul style="list-style-type: none"> ● Check with your doctor before you receive any vaccines. ● Use a reliable method of contraception during treatment with IBRANCE. ● It is important to tell your doctor if you get symptoms of an infection.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not lower the dosage or stop using IBRANCE without checking with your doctor. ● Do not eat grapefruit or drink grapefruit juice while you are being treated with IBRANCE.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful before you drive or use any machines or tools until you know how IBRANCE affects you. ● The effects on your ability to drive and use machines whilst taking

	this medicine are not known.
Looking after your medicine	<ul style="list-style-type: none">• Keep IBRANCE in a cool dry place where the temperature stays below 30°C.• Keep your medicine in the pack until it is time to use it in order to protect it from light.

For more information, see Section [5. What should I know while using IBRANCE?](#) in the full CMI.

6. Are there any side effects?

IBRANCE can make you more likely to get infections or make any infection that you may have worse.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

IBRANCE®

Active ingredient(s): *Palbociclib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using IBRANCE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using IBRANCE.

Read this leaflet carefully before you use IBRANCE and keep it with the medicine. You may need to read it again.

Where to find information in this leaflet:

- [1. Why am I using IBRANCE?](#)
- [2. What should I know before I use IBRANCE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use IBRANCE?](#)
- [5. What should I know while using IBRANCE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using IBRANCE?

IBRANCE contains the active ingredient palbociclib. IBRANCE belongs to a group of medicines called cyclin-dependent kinase inhibitors.

IBRANCE is used to treat patients with hormone receptor-positive (HR-positive), human epidermal growth factor receptor 2 negative (HER2-negative) advanced breast cancer. It is given together with an aromatase inhibitor or fulvestrant, which are used as hormonal anticancer therapies.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

IBRANCE is only available with a doctor's prescription.

It is not addictive.

The safety and efficacy of IBRANCE in children has not been established.

2. What should I know before I use IBRANCE?

Warnings

Do not take IBRANCE if:

1. you are allergic to palbociclib, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- have had abnormal blood test results.

Decreased numbers of white blood cells, red blood cells and platelets are very common while you are being treated with IBRANCE. Your doctor will monitor you with regular blood tests to check for changes in the levels of your blood cells.

Low numbers of white blood cells can increase your risk of infection. Low numbers of red blood cells can increase tiredness and shortness of breath and make

your skin paler than normal. Low numbers of platelets can increase your risk of bleeding.

- have had fever, chills or any other signs or symptoms of infection.

Patients taking IBRANCE are predisposed to infections because they very commonly experience a decrease in white blood cells which affects how well their immune system works.

- have had a cough, shortness of breath, wheezing, dizziness or a blue tinge to your fingertips, skin or lips. Severe, life-threatening and fatal cases of pneumonitis and Interstitial Lung Disease (ILD) (inflammation of the tissues of the lungs and inflammation of the lining of cells the lungs resulting in scarring) have been reported in patients taking IBRANCE. It is important you pay attention to new or worsening symptoms that affect your breathing and tell your doctor.
- have or have had kidney problems
- have or have had liver problems
- lactose intolerance
- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

You should have a blood test before starting treatment with IBRANCE.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

IBRANCE may affect the developing baby and should not be taken during pregnancy.

Use contraception (birth control) to prevent pregnancy while you are being treated with IBRANCE.

Women who could become pregnant or men who could father a child must use a reliable method of contraception during treatment with IBRANCE. Women should continue using contraception for at least a month after taking their last dose of IBRANCE and males should continue using contraception for 14 weeks after the last dose of IBRANCE.

Tell your doctor immediately if you become pregnant while taking IBRANCE.

Tell your doctor if you are breastfeeding.

You should not breastfeed if you are being treated with IBRANCE.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and IBRANCE may interfere with each other.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat fungal infections such as posaconazole, voriconazole, ketoconazole, miconazole or itraconazole
- antibiotics used to treat bacterial infections such as erythromycin or clarithromycin
- medicines used to treat HIV infections/AIDS such as atazanavir, indinavir, efavirenz, ritonavir, lopinavir, fosamprenavir, nevirapine, etravirine or saquinavir
- medicines used to treat hepatitis C such as elbasvir/grazoprevir
- medicines used to treat tuberculosis (TB) such as rifampin or rifabutin,
- medicines used to treat certain heart conditions or high blood pressure such as bosentan or diltiazem
- medicines used to treat epilepsy, seizures or fits such as phenytoin, carbamazepine, felbamate, primidone or phenobarbital
- St John's wort (*Hypericum perforatum*), a herbal medicine used to treat depression and other conditions
- nefazodone, used to treat depression
- modafinil, used to treat sleep disorders

Tell your doctor if you are taking any other medicines to treat your condition.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IBRANCE.

4. How do I take IBRANCE?

IBRANCE is taken orally as a single tablet and swallowed whole.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label or in this leaflet, ask your doctor or pharmacist for help.

Always take IBRANCE exactly as your doctor has instructed you.

Check with your doctor or pharmacist if you are not sure.

How much to take

Advanced Breast Cancer

- The usual dose of IBRANCE for adults with advanced breast cancer is one 125 mg tablet taken once daily for 21 days followed by 7 days without taking IBRANCE.
- Your doctor may change your dose during treatment.

- Taking IBRANCE for 21 continuous days followed by 7 days without taking IBRANCE (total of 28 days) is counted as one treatment cycle.
- The 7-day break when you are not taking IBRANCE helps your body recover. It reduces your chance of getting side effects and could stop you getting an infection.
- Other medicines will be prescribed by your doctor to be taken while you are being treated with IBRANCE.

How to take IBRANCE

- IBRANCE is swallowed whole with a glass of water.
- **Do not chew, crush or split the tablets prior to swallowing.**

How long to take IBRANCE

- Keep taking IBRANCE for as long as your doctor tells you.
- This medicine helps control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.
- Ask your doctor if you are not sure how long to take this medicine for.

If you forget to take IBRANCE or vomit after taking a dose

Take your next dose at your regular time.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much

If you think that you have taken too much IBRANCE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Always take the outer carton of the medicine with you.

5. What should I know while using IBRANCE?

Things you should do

Make sure you follow your doctor's instructions and keep all appointments.

You should have a blood test before each treatment cycle.

The blood test is done to make sure your blood cells have recovered from the last treatment cycle and to check for side effects.

Tell your doctor immediately if you experience signs or symptoms of an infection such as fever and chills.

IBRANCE may reduce the number of your white blood cells and weaken your immune system. You may be at greater risk of getting an infection while you are taking IBRANCE.

Call your doctor straight away while taking IBRANCE if you:

- Develop a fever
- Become pregnant

If you are about to be started on any new medicine, tell your doctor you are using IBRANCE.

Remind any doctor, pharmacist or dentist you visit that you are using IBRANCE.

If you are going to have surgery, tell all doctors that you are taking IBRANCE. It may affect other medicines used during surgery.

Keep all your doctor's appointments so that your progress can be checked.

Things you should not do

- Do not give IBRANCE to anyone else, even if they have the same condition as you.
- Do not use IBRANCE to treat any other complaints unless your doctor tells you to.
- Do not stop using IBRANCE or lower the dosage without checking with your doctor.
- Do not eat grapefruit or drink grapefruit juice while you are being treated with IBRANCE.

Grapefruit and grapefruit juice may change the amount of IBRANCE in your body.

Things to be careful of

- You might get infections, including chest infections, more easily while you are receiving IBRANCE treatment. These infections may be serious.
- Your doctor may recommend you pause or discontinue IBRANCE treatment if you develop a severe or recurring infection, or if your blood tests show your white blood cells, red blood cells or platelets remain low for a prolonged period.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how IBRANCE affects you.

The effects on your ability to drive and use machines whilst taking this medicine are not known. Be careful driving or operating machinery until you know how IBRANCE affects you.

This medicine may cause fatigue and blurred vision in some people. If you have any of these symptoms do not drive, operate machinery, or do anything else that could be dangerous.

Looking after your medicine

Keep your medicine in the pack until it is time to use it to protect it from light. If you take the tablets out of the pack, they may not keep well.

Keep IBRANCE in a cool dry place where the temperature stays below 30°C. Do not store IBRANCE or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car. Heat and dampness can destroy some medicines.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

Keep it where children cannot reach it.

A locked cupboard at least 1.5 metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<p>Blood related issues</p> <ul style="list-style-type: none">• Bleeding or bruising more easily than usual• Low white blood cell, red blood cell or platelet cell counts <p>Gastrointestinal issues</p> <ul style="list-style-type: none">• Nausea (feeling sick), diarrhoea or vomiting• Redness, irritation, sores or swelling of the mouth, cheeks, gums and lips <p>Metabolism and nutrition disorders</p> <ul style="list-style-type: none">• Loss of appetite	<p>Speak to your doctor if you have any of these more common side effects and they worry you.</p> <p>They are usually mild and short-lived.</p>

Common side effects	What to do
<p>Skin related issues</p> <ul style="list-style-type: none"> • Hair thinning or loss • Skin rash, dryness or redness <p>General disorders and administration site conditions</p> <ul style="list-style-type: none"> • Fatigue, tiredness, lack of energy • Fever • Feeling of weakness in your muscles <p>Nervous system</p> <ul style="list-style-type: none"> • Unpleasant or unusual taste in your mouth 	

Serious side effects

Serious side effects	What to do
<p>Allergic type reactions</p> <ul style="list-style-type: none"> • Chest tightness • Shortness of breath, wheezing or difficulty breathing 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Swelling of the face, lips, tongue or other parts of the body ● Hives, itching or skin rash. <p>Infection issues</p> <ul style="list-style-type: none"> ● Signs and symptoms suggestive of an infection such as fever, chills, listlessness, paleness. ● Signs and symptoms of an infection in your chest may also include discomfort in your chest, dizziness, breathlessness, rapid heart rate and weakness. ● Signs of soft tissue infection, such as a bump or open sore that doesn't heal <p>Blood related issues</p> <ul style="list-style-type: none"> ● Signs and symptoms suggestive of a blood disorder such as persistent fever, 	

Serious side effects	What to do
bruising, bleeding very easily, paleness.	

Laboratory results

Some side effects observed with IBRANCE may not have symptoms and may only be discovered through blood tests. These include, most commonly, low levels of white blood cells and red blood cells and platelets in the blood.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What IBRANCE contains

Active ingredient (main ingredient)	Palbociclib
Other ingredients (inactive ingredients)	<p>The tablets have a tablet core containing:</p> <p>microcrystalline cellulose silicon dioxide crospovidone magnesium stearate succinic acid</p> <p>The tablets also have a film coating containing:</p> <p>hypromellose titanium dioxide (E171) triacetin indigo carmine aluminium lake (E132) iron oxide red (E172)</p>

	iron oxide yellow (E171)
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Do not take this medicine if you are allergic to any of these ingredients.

What IBRANCE looks like

IBRANCE 75 mg Tablet

IBRANCE 75 mg Tablet is round, light purple, film-coated tablet debossed with “Pfizer” on one side and “PBC 75” on the other side. AUST R 319780

IBRANCE 100 mg Tablet

IBRANCE 100 mg Tablet is oval, green, film-coated tablet debossed with “Pfizer” on one side and “PBC 100” on the other side. AUST R 319782

IBRANCE 125 mg Tablet

IBRANCE 125 mg Tablet is oval, light purple, film-coated tablet debossed with “Pfizer” on one side and “PBC 125” on the other side. AUST R 319784

Each tablet blister pack contains 21 film-coated tablets.

IBRANCE does not contain sucrose, gluten, tartrazine or any other azo dyes.

Who distributes IBRANCE

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

This leaflet was prepared in June 2022.

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