

IBRANCE
palbociclib



Your IBRANCE treatment guide

ABOUT THIS GUIDE

Every moment is precious and if you are reading this guide it means you have been prescribed **IBRANCE**, a medicine that may help you get as many of those moments as you can.

IBRANCE is a therapy for treating hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced or metastatic breast cancer (mBC).

IBRANCE is taken in combination with hormonal (or endocrine) anticancer therapy, so you will have also been prescribed either an aromatase inhibitor (AI, e.g. letrozole, anastrozole and exemestane) or fulvestrant as part of your treatment regimen.

This guide aims to:

- **provide you with information** about treating mBC with IBRANCE
- **explain** how to take IBRANCE
- **help you manage** some possible side effects with IBRANCE

Your healthcare teams and local patient support groups can also provide connections to others with mBC, advice, understanding, help and support.

This guide does not contain all the available information, and does not take the place of talking to your doctor or healthcare team. If you have any questions about taking this medicine, please speak to your doctor or healthcare team.

Your details:

Your name: _____

Oncologist's name: _____

Contact details: _____

IBRANCE regimen

- with aromatase inhibitor
(e.g. letrozole, anastrozole and exemestane)
- with fulvestrant

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ABOUT mBC AND ITS TREATMENT

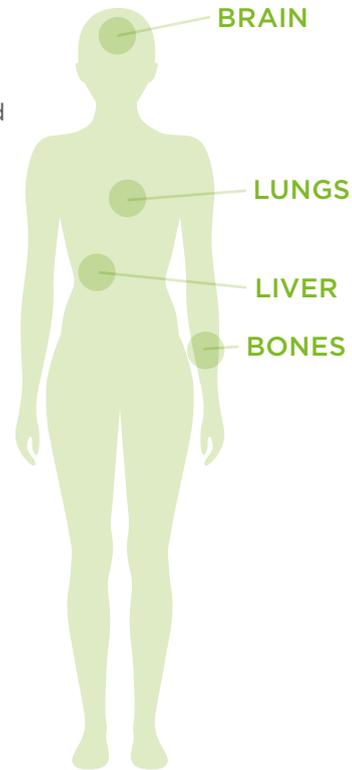
WHAT IS mBC?

mBC, also known as stage IV or advanced breast cancer, occurs when cancer has spread beyond the breast and nearby lymph nodes to other organs, like the lungs, bones, liver or brain.² These distant cancer sites are called metastases.³

As tumour cells have spread to other parts of the body, systemic therapy – which treats the whole body, is the mainstay of treatment. The goals of this treatment are to help control the spread of cancer in your body and maintain your quality of life.³

HR+/HER2- mBC

If your breast cancer subtype is HR+, your cancer cells may grow in response to either the hormone estrogen or progesterone, or both, and are more likely to respond to **endocrine therapies (ET) such as aromatase inhibitors or fulvestrant.**³ HR+ is the most common subtype of breast cancer, representing over 60% of all cases.^{3,4}



WHAT IS IBRANCE?

IBRANCE belongs to a group of medicines called cyclin-dependant kinase inhibitors or CDK inhibitors. It is used to treat a certain type of breast cancer called hormone receptor positive (HR+), human epidermal growth factor receptor 2 (HER2) negative advanced breast cancer.

It is given together with an aromatase inhibitor (AI) (letrozole, anastrozole and exemestane) or in combination with fulvestrant for patients who have received prior endocrine therapy.

If you have not gone through menopause, you may also be prescribed a treatment called a luteinising hormone blocker that medically induces menopause which stops the ovaries producing estrogen⁵.

HOW TO TAKE IBRANCE¹

It is important that you take IBRANCE exactly as prescribed by your healthcare team.⁶ Here are a few helpful reminders:

-  Ensure you always take IBRANCE with food, preferably a meal.¹
-  Take IBRANCE at approximately the same time every day.¹
-  Swallow your IBRANCE capsules whole with a glass of water (do not chew, crush, or open them prior to swallowing). Do not ingest a capsule if it is broken, cracked or otherwise not intact.⁶
-  If you vomit or miss a dose, do not take an additional dose. Take your next prescribed dose as scheduled.¹
-  Avoid grapefruit and grapefruit juice while taking IBRANCE.⁶
-  Tell your doctor if you are taking, have recently taken, or might take any other medicines, including complementary supplements like vitamins, as IBRANCE may affect the way some medicines work and vice versa.⁶
-  Keep your capsules in a cool dry place where the temperature stays below 30°C.⁶
-  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.⁶

In order to help ensure you take IBRANCE correctly, your healthcare team may give you an IBRANCE Dosing Tracker or tell you about CareMate mBC so you can easily track the days you need to take IBRANCE.

IBRANCE IS TAKEN ORALLY ONCE DAILY WITH FOOD OVER A 4-WEEK CYCLE¹

For the first **3 weeks (21 days)**, you take one IBRANCE capsule every day.

Then in the **last week (7 days)**, you stop taking IBRANCE.

At the end of 4 weeks, the cycle will start over again.

4-WEEK CYCLE				
	WEEK 1	WEEK 2	WEEK 3	WEEK 4
 IBRANCE (once daily with food)	✓	✓	✓	✗
 AI, e.g. Letrozole (once daily with food) OR	✓	✓	✓	✓
 Fulvestrant (one injection on day 1*)	✓	✗	✗	✗

*For the first cycle only, you will also receive a fulvestrant injection on day 15.

If you take IBRANCE with an aromatase inhibitor (AI), e.g. letrozole, anastrozole or exemestane

You take your AI pill every day throughout the entire 4-week cycle – even during the last week when you stop taking IBRANCE. It's important you continue to take your AI even if your healthcare team stops your treatment with IBRANCE or adjusts your IBRANCE dose.¹

If you take IBRANCE with fulvestrant

You will receive an injection from your healthcare provider on the first day of every 4-week cycle. Additionally, for the first cycle only, you will also receive a second injection on day 15 of your therapy.¹

SIDE EFFECTS YOU MAY EXPERIENCE WITH IBRANCE¹

Like all medicines, **IBRANCE may cause side effects**, although not everybody gets them. A list of some side effects that could occur while taking IBRANCE can be found in the IBRANCE Consumer Medicine Information (CMI) leaflet provided by your Healthcare Professional or available online at www.medsafe.govt.nz/Consumers/cmi/i/ibrance.

Talk to your doctor if you experience side effects of any kind, even if they are not listed in this guide.⁶

The most common side effect with IBRANCE is a low white blood cell count (this is called neutropenia).

Other very common side effects include¹:

- Reduction in red blood cells and blood platelets
- Infections
- Feeling tired
- Decreased appetite
- Inflammation of the mouth and lips (stomatitis)
- Nausea
- Vomiting
- Diarrhoea
- Rash
- Hair loss

Other side effects not listed above may also occur in some people.

MONITORING YOUR THERAPY

Your doctor will ask you to attend regular visits to discuss with you how you are feeling and monitor for possible side effects.

Your healthcare team will test your blood before you start taking IBRANCE and at the beginning of the 4-week cycle.¹

Additionally, your blood will be tested on day 15 of the first two treatment cycles. If your blood results indicate that you have low white blood cells, your healthcare team may pause or adjust your IBRANCE dose.¹

At the end of this guide, you will find an IBRANCE **Complete Blood Count Reminder Card** that will help you keep track of your blood test appointments that have been scheduled during your treatment. It's **very important** that you take this card with you on every visit, so that your healthcare team can schedule your blood tests appropriately and ensure your therapy is being correctly monitored.

For AI- or fulvestrant-related side effects, please refer to the CMI of your respective treatment found at www.medsafe.govt.nz

MANAGING POSSIBLE SIDE EFFECTS WITH IBRANCE*



REDUCTIONS IN WHITE AND RED BLOOD CELLS AND BLOOD PLATELETS

There are many types of cells within your blood that have specific roles for a whole range of daily functions. These include: fighting infections, preventing blood clots, wound healing and carrying oxygen to your organs. One of these cell types responsible for fighting infection, called white blood cells, is potentially affected by many drugs – including IBRANCE. These changes are temporary and can be well managed by your oncologist. As such, regular monitoring of these cells through a simple blood test is required, particularly when you first start this medication and the next few months after that.^{1,5}

Typically, a low white blood cell count does not cause any specific symptoms, and is rarely associated with fever. However, if your blood test results show that your **white blood cell count (neutrophils) is low, your doctor may pause your treatment with IBRANCE or reduce the dose of IBRANCE to help your white blood cell count recover.**¹

Contact your doctor straight away if you develop any of the following, which might be associated with a low blood cell count:^{1,5}

- Fever
- Chills
- Weakness
- Shortness of breath
- Bleeding
- Easy bruising



INFECTIONS

It's important to **take steps to protect yourself against infection** throughout your treatment:

- Promptly report signs/symptoms of infection, such as fever or chills^{1,5,8}
- Avoid crowded places and do not visit people who might have infections, coughs or fevers, especially if your doctor tells you your white blood cell count is low⁷
- Maintain good hygiene, e.g. wash your hands often, particularly before preparing food or eating⁷
- Wash vegetables, salads and fruit well before eating or cooking⁵

*This section of the guide does not include management tips for all the most common side effects that you may experience with IBRANCE, but those which we consider may be more relevant to you.



HAIR LOSS

Obvious hair loss with IBRANCE is rare, although hair thinning may occur. **If hair thinning occurs, these tips may help:**^{1,5}

- Use gentle hair products such as baby shampoos
- Avoid harsh chemicals like hair dye and chemical straighteners
- Be gentle when brushing and washing hair
- Avoid too much hair brushing or pulling (braids or ponytails)
- Avoid using hair dryers, curling tongs and curlers and pat your hair dry
- Wear a hat or scarf outside to reduce loss of body heat
- Try a different hairstyle to cover areas of hair thinning or loss



DIARRHOEA

If you experience diarrhoea, tell your healthcare team. They may decide to give you a specific treatment to treat diarrhoea if necessary. But also take a closer look at your diet. Certain foods and drinks can make diarrhoea worse or better. **Following these tips may help to alleviate diarrhoea symptoms:**^{5,7,8}

- Drink plenty of clear liquid (e.g. water, weak tea, apple juice, clear broth) to replace lost fluids
- Eat small, frequent meals instead of three large ones
- Avoid greasy foods, bran, raw fruits and vegetables, caffeine, very hot or spicy foods, milk or milk products
- Eat foods high in potassium (e.g. bananas, potatoes, apricots)
- Don't drink alcohol or use tobacco
- When the diarrhoea starts to improve, try eating small amounts of foods that are easy to digest such as rice, bananas, apple sauce, yoghurt, mashed potatoes, low fat cottage cheese, and dry toast



NAUSEA

If you're feeling sick or are vomiting, it's best to talk to your healthcare team. They can tell you how to deal with your symptoms or may prescribe you medication that can help. In addition to your healthcare team's instructions, **following these tips may help you feel better:**^{5,6,7}

- Eat small, frequent meals instead of three large ones
- Try high-calorie foods that are easy to eat (desserts, ice cream, yoghurt, etc.) several times a day
- Avoid fried food, fatty foods or foods with a strong smell
- Eat bland foods, such as dry toast or crackers
- Sip water throughout the day, as dehydration may contribute to nausea
- Use relaxation techniques, such as deep breathing
- When experiencing nausea, use distraction such as music, television or talking with friends



FEELING TIRED

During treatment you go through a lot, both physically and mentally. This could leave you feeling tired or weak. **By following these tips, you may be able to increase your energy:**^{5,7,9}

- Together with your healthcare team, build a schedule to make sure you are getting enough rest and activity
- Try doing light exercise each day as this can give you more energy
- Take short rests or breaks
- Don't push yourself too hard, rest when you begin to feel tired
- Eat a well-balanced diet and drink plenty of fluids. Sometimes tiredness and weakness can be caused by dehydration
- Plan important activities for when you have the most energy
- Ask others to help with chores
- Do things that are relaxing, such as listening to music, reading or meditating
- Support groups may be able to help you manage stress, and work through things that are making you tired

RECORDING HOW YOU FEEL WITH IBRANCE

Always tell your doctor or healthcare team about any side effects you may be experiencing.

There are supplemental treatments available that may help with the side effects – or they may want to adjust your treatment.

At the back of this guide you will find a diary that will help you record any possible side effects you may experience, and when they happen. The diary covers 1 cycle (28 days) of IBRANCE treatment, two weeks per page.

We encourage you to discuss your diary when you next visit your healthcare provider, so that they can accurately assess how you are getting on while taking IBRANCE.

Before you start treatment, your healthcare team will give you instructions on how to take IBRANCE and potential IBRANCE side effects you may experience.

If you want further information, please contact your healthcare team and inform them of any questions you may have regarding your IBRANCE treatment.

YOUR IBRANCE DIARY

REGIMEN: IBRANCE + _____
 (add in the name of endocrine therapy prescribed)

Week 1			
Date	Time (am/pm)	Side effect	Severity on a scale of 1 (mild) to 10 (severe)

How I felt this week (overall summary)

Week 2			
Date	Time (am/pm)	Side effect	Severity on a scale of 1 (mild) to 10 (severe)

How I felt this week (overall summary)

Points to discuss with my doctor

Week 3

Date	Time (am/pm)	Side effect	Severity on a scale of 1 (mild) to 10 (severe)

How I felt this week (overall summary)

Week 4

Date	Time (am/pm)	Side effect	Severity on a scale of 1 (mild) to 10 (severe)

How I felt this week (overall summary)

Points to discuss with my doctor

References: **1.** IBRANCE (palbociclib) Data Sheet **2.** Cancer Research UK. TNM breast cancer staging. <http://www.cancerresearchuk.org/about-cancer/type/breast-cancer/treatment/tnm-breast-cancer-staging>. Accessed September 2016. **3.** ESMO. Breast Cancer: A guide for patients. <http://www.esmo.org/Patients/Patient-Guides/Breast-Cancer>. Accessed September 2016. **4.** American Cancer Society. Hormone therapy for breast cancer. <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-treating-hormone-therapy>. Accessed September 2016. **5.** Cancer Research UK. Breast cancer. <http://www.cancerresearchuk.org/about-cancer/type/breast-cancer/>. Accessed September 2016. **6.** IBRANCE Consumer Medicine Information Leaflet. **7.** American Cancer Society. Caring for the patient with cancer at home: a guide for patients and families. <http://www.cancer.org/treatment/treatmentsandsideeffects/physicalsideeffects/dealingwithsymptomsathome>. Accessed September 2016. **8.** Mayo Clinic. Diarrhea: cancer-related causes and how to cope. <http://www.mayoclinic.org/diseases-conditions/cancer/in-depth/diarrhea/art-20044799>. Accessed September 2016. **9.** American Cancer Society. Managing cancer-related fatigue. <http://www.cancer.org/treatment/treatmentsandsideeffects/physicalsideeffects/fatigue/seven-ways-to-managecancer-related-fatigue>. Accessed September 2016.

IBRANCE® (palbociclib 75 mg, 100 mg and 125 mg) Capsules

IBRANCE (palbociclib) is a funded prescription medicine used to treat HR+, HER2- advanced breast cancer taken in combination with an aromatase inhibitor or fulvestrant.

IBRANCE has risks and benefits. Do not take IBRANCE if you are allergic to palbociclib or any of the other ingredients in IBRANCE capsules. Caution is needed if you are premenopausal or perimenopausal, have or have had abnormal blood test results, respiratory infections or problems with your lungs, problems with your liver or kidneys, are lactose intolerant, are pregnant or planning to become pregnant or are breastfeeding. Tell your doctor if you are taking any other medicines. Common side effects include infection, abnormal blood test results, tiredness, feeling sick or vomiting, diarrhoea, sore mouth, lips or tongue, hair loss, loss of appetite, nose bleed, skin rash, change in sense of taste, blurred vision, increased tearing or dry eyes, shortness of breath, bleeding or bruising more easily than usual. If symptoms continue or you have side effects, see your doctor, pharmacist or healthcare professional. Ask your doctor if IBRANCE is right for you. Use strictly as directed. Contains 75 mg, 100 mg or 125 mg of palbociclib.

IBRANCE is funded. A pharmacy charge and normal doctor's fees apply for all prescriptions.

Further information on IBRANCE is available from Medsafe www.medsafe.govt.nz or Pfizer New Zealand Limited, Auckland, www.pfizer.co.nz Ph. 0800 736 363. V10120

Pfizer New Zealand Limited, Auckland

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