PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

IBRANCE 75 mg Capsules

IBRANCE 100 mg Capsules

IBRANCE 125 mg Capsules

Palbociclib

Contains sugar

Each IBRANCE 75 mg capsule contains 55,78 mg lactose monohydrate.

Each IBRANCE 100 mg capsule contains 74,37 mg lactose monohydrate.

Each IBRANCE 125 mg capsule contains 92,96 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking IBRANCE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, or other health care provider.
- IBRANCE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What IBRANCE is and what it is used for

IBRANCE is an anticancer medicine containing the active substance palbociclib.

IBRANCE works by blocking proteins called cyclin-dependent kinase 4 and 6, which regulate cell growth and division. Blocking these proteins can slow down growth of cancer cells and delay the progression of your cancer.

IBRANCE is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination

- with letrozole as initial endocrine-based therapy in postmenopausal women
- with fulvestrant in women with disease progression who have received prior endocrine therapy

2. What you need to know before you take IBRANCE

Do not take IBRANCE

- if you are hypersensitive (allergic) to palbociclib or any of the other ingredients of IBRANCE (listed in section 6).

Warnings and precautions

Take special care with IBRANCE

Tell your doctor, pharmacist or other health care provider if you have fever, chills or any other signs or symptoms of infection.

IBRANCE may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. Tell your health care provider right away if you have any new or worsening symptoms including:

- difficulty breathing or shortness of breath
- dry cough
- chest pain

Children

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

Other medicines and IBRANCE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Medicines that increase the amount of IBRANCE in your blood

Simultaneous administration with potent isoenzyme CYP3A inhibitors (e.g. lopinavir, indinavir, nelfinavir, ritonavir, telaprevir, and saquinavir used to treat HIV infection/AIDS; telithromycin antibiotic used to treat bacterial infections; voriconazole, itraconazole, ketoconazole, and posaconazole used to treat fungal infections and nefazodone used to treat depression) should be avoided.

Medicines that decrease the amount of IBRANCE in your blood

The concomitant administration with strong CYP3A inducers e.g. phenytoin, carbamazepine and rifampicin, St. John's Wort or moderate CYP3A inducers e.g. bosentan, efavirenz, etravirine, modafinil and nafcillin should be avoided.

IBRANCE with food and drink

During IBRANCE therapy, avoid eating grapefruit and products containing grapefruit. Grapefruit may increase your plasma concentration of IBRANCE.

Take IBRANCE with food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

- IBRANCE may have an adverse effect on the foetus.

- Women of childbearing potential who take IBRANCE, as well as partners of women on IBRANCE must use effective contraception during the therapy and for at least 14 weeks after IBRANCE is discontinued.

- If you are breastfeeding or plan to breastfeed. It is unknown whether IBRANCE is excreted in human breast milk. Together with your doctor, you should decide whether you will continue the use of IBRANCE or breastfeed. You should not do both concurrently.

Based on the results from animal studies, male fertility can be affected by IBRANCE therapy.

Driving and using machines

IBRANCE may make you feel tired or dizzy, you should exercise caution when driving or operating machinery.

It is not always possible to predict to what extent IBRANCE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which IBRANCE affects you.

IBRANCE contains lactose

If you have a hereditary galactose intolerance (the body is unable to absorb certain sugars), Lapp lactase deficiency (the body is unable to digest milk and milk products due to lack of an enzyme) or glucose-galactose malabsorption (the body is unable to absorb certain sugars), you should not take IBRANCE.

IBRANCE contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take IBRANCE

Do not share medicines prescribed for you with any other person.

Always take IBRANCE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment (Schedule 3/1) to comprise a complete cycle of 28 days.

When co-administered with IBRANCE, the recommended dose of letrozole is 2,5 mg taken orally once daily continuously throughout the 28-day cycle. Please refer to the patient information leaflet of letrozole.

When co-administered with IBRANCE, the recommended dose of fulvestrant is 500 mg administered intramuscularly on Days 1, 15, 29, and once monthly thereafter. Please refer to the patient information leaflet of fulvestrant.

IBRANCE should be taken with food.

Take your dose at approximately the same time each day.

Your doctor may modify the dose of IBRANCE based on your individual safety and tolerability profile, thus it is important to take IBRANCE exactly as instructed.

Your doctor will monitor your complete blood count before starting IBRANCE and on day 15 of the first 2 cycles and adjust the dosage if required.

If you vomit after taking a dose, do not take another dose. You should take the next prescribed dose at the usual time. IBRANCE capsules should be swallowed whole (do not chew, crush or open them prior to swallowing). No capsule should be ingested if it is broken, cracked, or otherwise not intact.

Special populations

Elderly population

No dose adjustment is necessary if you are 65 years of age or older.

Hepatic impairment

No dose adjustments are required if you have mild or moderate liver problems. If you have severe liver problems, the recommended dose of IBRANCE is 75 mg once daily for 21 consecutive days followed by 7 days off treatment (Schedule 3/1) to comprise a complete cycle of 28 days.

Renal impairment

No dose adjustments are required if you have mild, moderate or severe kidney problems.

Paediatric population

The safety and efficacy of IBRANCE in children and adolescents ≤ 18 years of age have not been established.

Your doctor will tell you how long your treatment with IBRANCE will last. Do not stop treatment early. If you have the impression that the effect of IBRANCE is too strong or too weak, tell your doctor or pharmacist.

If you take more IBRANCE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take IBRANCE

Do not take a double dose to make up for forgotten individual doses. You should take the next prescribed dose at the usual time.

4. Possible side effects

IBRANCE can have side effects.

Not all side effects reported for IBRANCE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IBRANCE, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Signs or symptoms of infection, such as fever or chills.
- Signs and symptoms of low red blood cell or blood platelet count, such as dizziness, shortness of breath, weakness, bleeding or easier formation of bruises and nose bleeding.
- difficulty breathing, dry cough or chest pain which could be a sign of inflammation of the lungs.

These are all serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice the following:

Frequent side effects

- decreased appetite
- nose bleeds
- stomatitis (inflammation inside the mouth, mouth sores, mouth pain, sore throat and discomfort)
- nausea
- diarrhoea
- vomiting
- rash
- tiredness
- weakness
- fever
- blurred vision

- dry eyes
- metallic taste in the mouth
- dry skin

Less frequent side effects

- inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints and fever (Cutaneous Lupus Erythematosus [CLE]).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via **the "6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of IBRANCE.

5. How to store IBRANCE

Store all medicines out of reach of children.

Store at or below 30 °C.

- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IBRANCE contains

- The active substance is palbociclib.

IBRANCE 75 mg: each capsule contains 75 mg palbociclib.

IBRANCE 100 mg: each capsule contains 100 mg palbociclib.

IBRANCE 125 mg: each capsule contains 125 mg palbociclib.

- The other ingredients are microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, and hard gelatin capsule shells.
  - The light orange, light orange/caramel, and caramel opaque capsule shells contain gelatin, red iron oxide, yellow iron oxide, and titanium dioxide.
  - The printing ink contains shellac, titanium dioxide, isopropyl alcohol, ammonium hydroxide, n-butyl alcohol, propylene glycol, and simethicone.

What IBRANCE looks like and contents of the pack

IBRANCE 75 mg: opaque, hard capsule with a light orange body/ light orange cap capsule imprinted with “PBC 75” on the body and “Pfizer” on the cap, in white ink. The capsule contains off-white to yellow powder.
IBRANCE 100 mg: opaque, hard capsule with a light orange body/caramel cap capsule imprinted with “PBC 100” on the body and “Pfizer” on the cap, in white ink. The capsule contains off-white to yellow powder.
IBRANCE 125 mg: opaque, hard capsule with a caramel body/caramel cap capsule imprinted with “PBC 125” on the body and “Pfizer” on the cap, in white ink. The capsule contains off-white to yellow powder.

IBRANCE is packed in high-density polyethylene bottles with polypropylene closures and heat induction seal liners, in a pack size of 21 capsules or in polychlorotrifluoroethylene/aluminum foil blister system as a unit dose of 1 capsule per cell.

Holder of Certificate of Registration

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