

IBRELYN

Palbociclib Capsules (75mg, 100mg and 125 mg)

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What IBRELYN is used for

IBRELYN is a prescription medicine used to treat hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic) in combination with:

- an aromatase inhibitor as the first hormonal-based therapy in women who have gone through menopause, or
- fulvestrant in women with disease progression following hormonal therapy

How IBRELYN works

IBRELYN belongs to the group of medicines called antineoplastics. IBRELYN interferes with the growth of cancer cells, which are eventually destroyed.

Before you use IBRELYN

- When you must not use it

It is not known if IBRELYN is safe and effective in children.

Pregnancy and lactation

Do not take IBRELYN if you are pregnant, trying to get pregnant or think you may be pregnant.

IBRELYN can harm your unborn baby. Females who are able to become pregnant and who take IBRELYN should use effective birth control during treatment and for at least 3 weeks after stopping IBRELYN.

Talk to your healthcare provider about birth control methods that may be right for you during this time.

If you become pregnant or think you are pregnant, tell your healthcare provider right away.

It is not known if IBRELYN passes into your breast milk. Do not take IBRELYN if you are breast-feeding or plan to breastfeed.

- Before you start to use it

Tell your doctor if you:

- have fever, chills, or any other signs or symptoms of infection.
- Experience dizziness, shortness of breath, weakness, or any increased tendency to bleed and/or to bruise.
- have liver or kidney problems.
- Are pregnant, or plan to become pregnant.
- have any other medical conditions.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription medicines, over-the-counter drugs, vitamins, and herbal products.

Some foods and other types of drugs can affect how CYP3A enzymes work. This can change the amount of cancer drug that you absorb. So, it

changes the dose of cancer drug that your doctor prescribed for you. This can affect how your cancer drug works, making it stronger or weaker.

You should inform your doctor if you are taking medicines containing:

- ketoconazole, itraconazole, voriconazole, posaconazole (used to treat fungal infections);
- clarithromycin, rifampin, telithromycin (used to treat infections);
- ritonavir, lopinavir, indinavir, nelfinavir, saquinavir, telaprevir, efavirenz, etravirine (used to treat viral infections);
- modafinil (used to treat excessive sleepiness);
- bosentan (used to treat high blood pressure in the vessels that carry blood to the lungs);
- verapamil (used to treat hypertension, chest pain, and heart rhythm disorders);
- phenytoin, carbamazepine (used to treat epilepsy and other neurological conditions);
- herbal preparations containing St. John's Wort (*Hypericum perforatum*) (used to treat depression and anxiety);
- cyclosporine, everolimus, sirolimus or tacrolimus (to prevent transplant rejection);
- midazolam (used to help you sleep or for anxiety);
- pimozone (used for treating mental illness);
- alfentanil, fentanyl (used as anaesthetic);
- quinidine (used for treating heart arrhythmia);
- ergotamine, dihydroergotamine (used to treat severe, throbbing headaches);

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- nefazodone (used to treat depression);
- nafcillin (used to treat bacterial infections).

How to use IBRELYN

- How much to use

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, ask your doctor or pharmacist for help.

Take one capsule of IBRELYN 125 mg orally once a day for 21 consecutive days, followed by 7 days without IBRELYN. Your doctor may adjust your dose as needed and tolerated.

If you have reached menopause, IBRELYN should be taken with food in combination with recommended dose of an aromatase inhibitor.

If you are having disease progression in spite of hormonal therapy, IBRELYN should be taken in combination with fulvestrant, the recommended dose of fulvestrant is 500 mg to be taken on days 1, 15, 29 and once in a month thereafter.

If you have not reached menopause or reaching menopause and taking IBRELYN plus fulvestrant therapy, then you should take luteinizing hormone releasing hormone (LHRH) agonists.

- When to use it

Use as directed by your doctor or pharmacist.

You can take the capsule with food at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

- How long to use it

Continue taking IBRELYN for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. If you miss a dose of IBRELYN or vomit after taking a dose of IBRELYN, do not take another dose. Take your next dose at your regular time.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking IBRELYN.

Tell your doctor immediately if you become pregnant while taking this medication.

IBRELYN should be swallowed whole with a glass of water. Do not chew, crush or open them prior to swallowing.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give IBRELYN to anyone else, even if they have the same symptoms or condition as you.

Do not take any capsules that have broken open, cracked, not intact or split.

Do not consume grapefruit products while on treatment with IBRELYN.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the capsules make you feel sick, dizzy, or tired, or give you a headache, do not drive or use machines and contact your doctor immediately

Side effects

Like all medicines, IBRELYN can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. IBRELYN may cause serious side effects, including:

- **Low white blood cell counts (neutropenia).** Low white blood cell Counts are common when taking IBRELYN. Your healthcare provider should check your white blood cell counts before and during treatment.

If you develop low white blood cell counts during treatment with IBRELYN, your healthcare provider may stop your treatment, decrease

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your dose, or may tell you to wait to begin your treatment cycles.

- Infection

IBRELYN may cause severe, life-threatening infections. Tell your healthcare provider right away if you develop any signs and symptoms of an infection such as fever or chills.

- Blood clots in the arteries of your lungs (pulmonary embolism or PE).

IBRELYN may cause serious or life-threatening blood clots in the arteries of your lungs. Tell your healthcare provider right away if you have any of the following signs and symptoms of a PE

- shortness of breath
- sudden, sharp chest pain that may become worse with deep breathing
- rapid heart rate
- rapid breathing

Other common side effects of IBRELYN include:

- tiredness
 - upper respiratory infection
 - nausea
 - numbness or tingling in your arms, hands, legs, and feet
 - sore mouth
 - lost sense of taste
 - unusual hair thinning or hair loss
 - diarrhea
 - decreased appetite
 - vomiting
 - inflammation of the mouth and lips
 - low blood platelet (certain type of blood cell) count
 - nosebleed
 - weakness
 - reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- You may report any side effects or adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of IBRELYN

- Storage

Keep out of the reach and sight of children.

Store below 30°C

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help to protect the environment.

Product Description

- What it looks like

Bottles of 21 capsules,
Blister of 10 capsules (3x10's) and
Blister of 7 capsules (1x7's)

IBRELYN 75: Yellow colored granular powder filled in size '2' hard gelatin capsule of light orange color cap imprinted with 'NAT' and light orange colour body imprinted with '75'.

IBRELYN 100: Yellow colored granular powder filled in size '1' hard gelatin capsule of caramel color cap imprinted with 'NAT' and light orange colour body imprinted with '100'.

IBRELYN 125: Yellow colored granular powder filled in size "0" hard gelatin capsule of caramel color cap imprinted with 'NAT' and caramel color body imprinted with '125'.

- Ingredients

Active ingredient(s): Palbociclib

Inactive ingredients: Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, hard gelatin capsule shells.

- MAL number:

IBRELYN 125 (Palbociclib Capsules 125mg) - MAL23116012AZ

IBRELYN 100 (Palbociclib Capsules 100mg) - MAL23116015AZ

IBRELYN 75 (Palbociclib Capsules 75mg) - MAL23116017AZ

Manufacturer

Natco Pharma Limited (Pharma-Division)
Kothur – 509228
Rangareddy District,
Telangana, India.

Product Registration Holder

Duopharma HAPI Sdn Bhd.
No.2 Jalan Saudagar U1/16,
Zon Perindustrian Hicom Glenmarie,
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