

# Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 06/2021

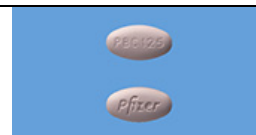
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

## Brand name: IBRANCE 125mg Tablets

**Active ingredient:** Palbociclib

**Dosage form:** pale purple tablet, major axis: 16.2 mm, minor axis: 8.6 mm, thickness: 5.7 mm

**Print on wrapping:** (Face) イブランス錠 125mg, IBRANCE Tablets, (Back) イブランス錠 125mg, IBRANCE, PBC 125



## Effects of this medicine

This medicine suppresses tumor growth by inhibiting cyclin dependent kinases 4 and 6 (CDK 4/6) and blocking progression of the cell cycle.

It is usually used to treat hormone receptor-positive and HER2-negative unresectable or recurrent breast cancer.

## Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.  
If you have: interstitial lung disease or its history or liver dysfunction.
- If you are pregnant, possibly pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

## Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is(( to be written by a healthcare professional))
- In combination with endocrine therapy, in general, for adults, take 1 tablet (125 mg of the active ingredient) at a time, once a day for 3 consecutive weeks. Then, discontinue taking this medicine for 1 week. This treatment cycle is repeated. The dosage may be decreased according to the condition. Strictly follow the instructions.
- If you miss a dose, skip the missed dose and take a dose at the regular time on the next day. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

## Precautions while taking this medicine

- Avoid taking any food containing St. John's wort (a kind of herb), since it may diminish medicinal effects.
- Avoid taking grapefruit juice with this medicine, since it may intensify the therapeutic effects of this medicine.
- If you or your partner have a possibility of pregnancy, avoid pregnancy while you are taking this medicine and for a certain period after you discontinue this medicine.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include alopecia, fatigue, stomatitis, nausea, joint pain, anemia, infection, hot flush, diarrhea, asthenia and rash. If any of these symptoms occur, consult with your doctor or pharmacist.

**The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.**

- anemia, fever, bleeding/bruise [myelosuppression]
- shortness of breath, breathing difficulty, dry cough, fever [interstitial lung disease]

**The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.**

## Storage conditions and other information

- Keep out of reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you dispose of unused medicines, seek advice of your pharmacy or medical institution about proper disposal of them.

## For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.