

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

Internal

Revised: 06/2022

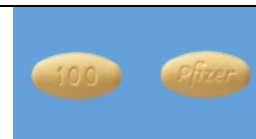
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name: Bosulif tablets 100mg

Active ingredient: Bosutinib hydrate

Dosage form: yellow tablet, major axis: approx. 10.6 mm, minor axis: approx. 5.5 mm, thickness: approx. 3.1 mm

Imprint or print on wrapping: ボシユリフ錠 100mg, ボシユリフ 100mg, Bosulif 100mg, Pfizer 100



Effects of this medicine

This medicine suppresses the abnormal growth of leukemia cells by inhibiting the activity of tyrosine kinase (Abl, Src).

It is usually used to treat chronic myelogenous leukemia (CML).

The following patients may need to be careful when 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 or foods. If you have heart disease or a history of it, a risk of prolonged QT interval or a history of it, or renal disease or liver disease.
- 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 general, for adults, take 5 tablets (500 mg of bosutinib) at a time, once a day, after a meal. However, for newly diagnosed chronic phase CML, the recommended dose is 4 tablets (400 mg) at a time. The dosage may be adjusted according to the condition. However, the maximum daily dose is 6 tablets (600 mg) at a time. Strictly follow the instructions.
- If you miss a dose, take the missed dose within 12 hours. If more than 12 hours have passed, skip the missed dose and follow your regular dosing schedule. 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

- Since this medicine may cause myelosuppression, infection or bleeding, blood test is periodically performed. In that case, undergo the test at specified dates and times.
- Since this medicine may cause body fluid retention, measure your weight regularly. If you notice abnormal weight gain, contact your doctor.
- Since the content of grapefruit may increase the blood level of this medicine and exacerbate adverse reactions, avoid taking at the same time.
- Since the foods containing St. John's wort (a kind of herb) may decrease the blood level of this medicine and diminish medicinal effects, avoid taking at the same time.
- Since this medicine may cause dizziness, fatigue and vision disturbance, avoid driving a car and operating dangerous machinery.
- If you 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 diarrhea, nausea, vomiting, rash, abdominal pain, fatigue, decreased appetite, headache, itch, fever and asthenia. 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.

- general malaise, loss of appetite, yellowing of the skin and the white of eyes [hepatitis, liver dysfunction]
- muddy or watery stool [severe diarrhea]
- symptoms of anemia (dizziness on standing up, headache, etc.), fever, bleeding tendency (subcutaneous bleeding, nose bleeding, etc.) [myelosuppression (decreased platelets, anemia, decreased white blood cells, decreased

neutrophils, decreased granulocytes, etc.)]

- rapid weight gain, dyspnea [body fluid retention]
- pale face, dyspnea, consciousness disorder [shock, anaphylaxis]
- dizziness, palpitation, losing consciousness, chest pain, pressure in chest [heart disorder (prolonged QT interval, arrhythmia, myocardial infarction, atrial fibrillation, etc.)]
- fever, sore throat, abdominal pain [infection (nasopharyngitis, gastroenteritis, pneumonia, urinary infection, sepsis, etc.)]
- headache, abdominal pain, bleeding from the vagina/eyes/mouth [bleeding (cerebral hemorrhage, gastrointestinal hemorrhage, vaginal hemorrhage, eye hemorrhage, oral hemorrhage, etc.)]
- severe pain in the upper abdomen, back pain, nausea [pancreatitis]
- shortness of breath/breathing difficulty, dry cough, fever [interstitial lung disease]
- decreased urine output, edema, general malaise [renal failure]
- dyspnea, chest pain [pulmonary hypertension]
- decreased consciousness, decreased urine output, breathing difficulty [tumor lysis syndrome]
- red eyelids and eyes, lips and mouth sores, rash, blister, fever [toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiforme]

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 at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. Please consult with your pharmacy or medical institution, since proper disposal of the unused medicines requires attention. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.