

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

Internal

Revised: 11/2022

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:IMATINIB TABLETS 100mg 「OHARA」

Active ingredient:Imatinib mesilate

Dosage form:smoky yellowish red to dark yellowish red tablet, diameter: 7.6 mm, thickness: 3.3 mm

Imprint or print on wrapping:イマチニブ 100 mg 「オーハラ」, OH-31, Imatinib 100 mg 「OHARA」



Effects of this medicine

This medicine suppresses the proliferation of cancer cells by inhibiting abnormal action of tyrosine kinase (Bcr-Abl, KIT, FIP1L1-PDGFR alfa) involved in cell proliferation.

It is usually used to treat chronic myeloid leukemia, KIT (CD117)-positive gastrointestinal stromal tumor, Philadelphia chromosome-positive acute lymphocytic leukemia, FIP1L1-PDGFR alfa-positive hypereosinophilic syndrome or chronic eosinophilic leukemia.

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 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))

•For chronic myeloid leukemia: In general, for adults, take 4 tablets (400 mg as imatinib) at a time in the chronic phase and 6 tablets (600 mg) at a time in the accelerated/blast phase, once a day after meal. The dosage may be adjusted according to your blood test results or age/symptoms. However, the dosage may be increased up to 6 tablets (600 mg) at a time, once a day in the chronic phase and up to 4 tablets (400 mg) at a time, twice a day in the accelerated/blast phase.

For KIT (CD117)-positive gastrointestinal stromal tumor: In general, for adults, take 4 tablets (400 mg of imatinib) at a time, once a day after meal. It may be reduced according to your age or symptoms.

For Philadelphia chromosome-positive acute lymphocytic leukemia: In general, for adults, take 6 tablets (600 mg as imatinib) at a time, once a day after meal. The dosage may be decreased according to your blood test results, age/symptoms.

For FIP1L1-PDGFR alfa-positive hypereosinophilic syndrome or chronic eosinophilic leukemia: In general, for adults, take 1 tablet (100 mg of Imatinib) at a time, once a day after meal. It may be adjusted according to your symptoms. The dosage could be increased up to 4 tablets (400 mg).

In any case, strictly follow the instructions.

- When taking the medicine, take it with a glass of water or lukewarm water (about 200 cc) after meal.
- If you miss a dose, you should not take the missed dose immediately. Take a dose at your next 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

- Strictly follow the examination schedule instructed by your doctor. Measure your body weight regularly, and contact your doctor if you notice abnormal increases in your body weight.
- Avoid taking grapefruit juice with this medicine, since it may intensify the therapeutic effects of this medicine.
- Avoid taking health food containing St. John's Wort with this medicine, since it may diminish the therapeutic effects of this medicine.
- As this medicine may cause dizziness, drowsiness or foggy vision, pay attention when performing dangerous operations such as working at heights, driving a car or operating machinery.
- If you may possibly become pregnant, use birth control while taking this medicine and for a certain period after stopping.
- As it is recommended not to breastfeed while taking this medicine, make sure to consult

with the doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea/vomiting, diarrhea, loss of appetite, rash, superficial edema (face/eyelid/lower limbs, etc.), malaise, muscle spasm and fever. 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.

- anemic symptoms, fever, bleeding tendency [bone marrow suppression]
- headache, conscious disorder, hemiplegia [cerebral bleeding, subdural bleeding]
- melena/vomiting of blood, abdominal pain, abdominal bloating, anemia [gastrointestinal bleeding, gastric antral vascular ectasia, gastrointestinal perforation, tumor bleeding]
- increased body weight, chest pain, respiratory distress [serious body fluid retention]
- fever, dry cough, respiratory distress [interstitial pneumonia, pulmonary fibrosis]
- facial pallor, respiratory distress, conscious disorder [shock, anaphylaxis]
- anemia, bleeding tendency, decreased urine output [thrombotic microangiopathy]

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 the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of it, ask the pharmacy or medical institution on how to discard. Do not give it to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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