

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

Internal

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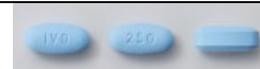
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name: TIBSOVO Tablets 250mg

Active ingredient: Ivosidenib

Dosage form: blue tablet, major axis: 18.0 mm, minor axis: 8.4 mm, thickness: 7.3 mm

Imprint or print on wrapping: IVO 250



Effects of this medicine

This medicine recovers differentiation of blood cells by inhibiting variant isocitrate dehydrogenase (IDH1) and then suppresses proliferation of leukemia cells.

It is usually used to treat acute myeloid leukemia with IDH1 gene mutation positive.

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 a possibility of having prolongation of QT interval or a history of prolongation of QT interval.
If you have liver disorder.
- If you are 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 2 tablets (500 mg of the active ingredient) at a time, once a day. The dosage may be decreased according to the conditions. Strictly follow the instructions.
- This medicine is used in combination with Azacitidine.
- IDH1 genetic mutation test (a test to check IDH1 genetic mutation, using bone marrow or blood), electrocardiogram and blood test are conducted before using this medicine.
- Avoid taking this medicine before and after taking fatty food.
- If you are taking any medicine which affects this medicine, the dosage of this medicine may be decreased.
- If you miss a dose, take the missed dose as soon as possible if it is within 12 hours of the scheduled time. If it is over 12 hours, skip the missed dose and continue 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 prolongation of QT interval may occur, ECG and electrolyte tests should be periodically conducted while using this medicine.
- Since differentiation syndrome may occur, blood test should be periodically conducted while using this medicine.
- Avoid taking any food including grapefruit or St. John's Wort because it may affect the medicinal effects of this medicine.
- Female patients with a possibility of pregnancy should use an adequate contraception while using this medicine and for 1 month after the completion of this medication. When using oral contraceptives, use a method other than oral contraceptives as well.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include prolongation of QT interval (dizziness, palpitation), differentiation syndrome, diarrhea, anemia, nausea, peripheral sensory neuropathy (numbness/pain of limbs), insomnia, fever and bone pain. 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.

- fever, breathing difficulty, shortness of breath, chest pain, rash [differentiation syndrome]
- dizziness, palpitations, faint [prolongation of QT interval]
- weakness in limbs on both sides, tripping when walking, double vision [Guillain-Barre syndrome]

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 at a room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- After opening the plastic bottle, do not take out the desiccant to avoid moisture, and store with the cap tightly closed after use.
- Discard the remainder. Do not store them. If you do not know how to discard, consult your pharmacy or medical institution about how to discard them. Do not give this medicine to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.