

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

Internal

Revised: 08/2022

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:**XOSPATA Tablets 40mg

**Active ingredient:**Gilteritinib fumarate

**Dosage form:**pale yellow tablet, diameter: approx. 7.1 mm, thickness: approx. 3.5 mm

**Imprint or print on wrapping:**ゾスパタ 40mg, house-mark, house-mark+235, アステラス製薬, XOSPATA 40mg



**Effects of this medicine**

This medicine suppresses growth of tumor cells by inhibiting FMS-like tyrosine kinase 3 (FLT3).

It is usually used for the treatment of patients with relapsed or refractory FLT3 mutation-positive acute myeloid 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 have a risk of prolonged QT interval or a history of it.
- 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 3 tablets (120 mg of gilteritinib) at a time, once a day. The dosage may be adjusted according to the condition, but it should not exceed 5 tablets (200 mg) at a time, once a day. Strictly follow the instructions.
- Examinations including FLT3 mutation test (using bone marrow or peripheral blood sample to determine if FLT3 mutations are present), electrocardiogram, electrolyte tests (potassium, magnesium, etc.), blood tests, liver function tests and renal function tests will be performed before using this medicine.
- If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, 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 prolonged QT interval may occur, electrocardiogram and electrolyte tests will be periodically performed while using this medicine.
- Since myelosuppression such as febrile neutropenia and anemia may occur, blood tests will be periodically performed while using this medicine.
- Since hemorrhage such as cerebral hemorrhage and subdural hematoma may occur, blood tests will be periodically performed while using this medicine.
- Since liver dysfunction may occur, liver function tests will be periodically performed while using this medicine.
- Since renal disorder such as acute kidney injury may occur, renal function tests will be periodically performed while using this medicine.
- Avoid taking any food containing St. John's wort (a kind of herb) with this medicine, since it may diminish medicinal effects.
- If you or your partner have a possibility of pregnancy, avoid pregnancy while you are using 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 anemia, nausea and diarrhea. 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 symptom, fever, bleeding tendency [myelosuppression]
- fever, general malaise, cold-like symptom [infection]
- headache, consciousness disturbance, hemiplegia [bleeding]
- chest pain, palpitation, chest discomfort [prolonged QT interval]
- chest pain, fever, palpitation, breathing difficulty [pericarditis, heart failure, pericardial effusion]

**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. If you do not know how to discard, seek advice of your dispensing pharmacy or medical institution. Do not give the unused medicines to others.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.