

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

Internal

Revised: 05/2020

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

Print on wrapping: (Face) ゾスパタ 40mg, ゾスパタ, 40 mg, house-mark, アステラス製薬, (Back) XOSPATA 40mg, ゾスパタ 40 mg, house-mark



Effects of this medicine

This medicine inhibits growth of tumor cells by suppressing FMS-like tyrosine kinase 3 (FLT 3).

It is usually used for the treatment of patients with relapsed or refractory acute myeloid leukemia who have FLT3 gene mutation positive.

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 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.
- 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

- Avoid taking any food containing St. John's wort (a kind of herb) with the medicine, because the effect of the medicine may be affected.
- 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 anemia, etc. 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 disorder, hemiplegia [bleeding]
- chest pain, palpitation, chest discomfort [prolonged QT interval]
- chest pain, fever, palpitation, respiratory distress [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 away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution how to discard.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.