

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

Internal

Revised: 08/2021

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: XALKORI Capsules 250mg

Active ingredient: Crizotinib

Dosage form: pale red/pale red capsule, diameter: 7.6 mm, length: 21.7 mm

Print on wrapping: (Face) ザーコリ 250, ザーコリ 250mg, (Back) 250, ザーコリ, CRZ250, XALKORI250mg



Effects of this medicine

This medicine has an anti-tumor effect by suppressing the effect of anaplastic lymphoma kinase (ALK) fusion protein and c-ros1 gene (ROS1) fusion protein, and then inhibiting the tumor cell growth.

It is usually used to treat unresectable advanced/recurrent non-small cell lung cancer positive for ALK fusion gene or ROS1 fusion gene.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itching, rash, etc.) to any medicines.
If you have: interstitial lung disease or its history, liver dysfunction, QT prolongation or its history or renal dysfunction.
- 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 1 capsule (250 mg of the active ingredient) at a time, twice a day. The dosage may be adjusted according to the conditions. Strictly follow the instructions.
- If you miss a dose, take the missed dose when you notice. If it is almost time for the next dose (within 6 hours before 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

- This medicine may cause foggy vision, double vision and focus disorder. Pay attention when you operate dangerous machinery, such as driving a car, while you are taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include vision disorder, nausea, diarrhea, vomiting and edema. 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.

- shortness of breath/breathing difficulty, dry cough, fever [interstitial lung disease]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [fulminant hepatitis, liver failure, liver dysfunction]
- chest pain, syncope, dizziness [QT prolongation, bradycardia]
- sudden high fever, sore throat, subcutaneous bleeding [blood disorder]
- rapid increase in body weight, breathing difficulty, edema [heart failure]

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. If you dispose of unused medicines, ask the pharmacy and the medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.