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

Internal

Published: 04/2022

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:LUMAKRAS Tablets 120mg

Active ingredient: Sotorasib

Dosage form:yellow tablet, major axis: 16.00 mm, thickness: 5.58 mm

Print on wrapping:

Effects of this medicine

This medicine is a KRAS G12C inhibitor. It suppresses the growth of non-small cell lung cancer (NSCLC) by selectively suppressing the action of KRAS G12C, a protein involved in the growth of cancer cells.

It is usually used for unresectable advanced/recurrent NSCLC with KRAS G12C mutation progressed after cancer chemotherapy.

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 liver 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 8 tablets (960 mg of the active ingredient) at a time, once a day. The dose may be decreased according to the condition. Strictly follow the instructions.
- If you miss a dose, take the missed does as soon as possible. If it is more than 6 hours from the scheduled time, skip the dose for that day and start the next dose from the next day. 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 this medicine may cause liver dysfunction, liver function tests are regularly conducted.
- Since the medicine may cause interstitial lung disease, initial symptoms such as shortness of breath, difficulty breathing, cough, and fever need to be checked as well as chest imaging while taking medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, nausea, vomiting, abdominal pain and fatigue. 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.

- easily fatigued, general dullness, weakness [liver dysfunction]
- fever, cough , difficulty breathing [interstitial lung disease]

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. Ask the pharmacy or medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.