

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

Internal

Revised: 07/2023

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:XOCOVA Tablets 125mg(Convex Tablets)

Active ingredient:Ensitrelvir fumaric acid

Dosage form:white to pale yellowish white tablet, diameter: 9.0 mm, thickness: 4.9 mm

Imprint or print on wrapping:(Face) ズコーバ 125mg, (Back) ズコーバ 125mg 711
125



Effects of this medicine

This medicine inhibits the 3CL protease of the novel coronavirus (SARS-CoV-2) and prevents processing polyprotein to inhibit viral replication.

It is usually used to treat infections caused by SARS-CoV-2.

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 decreased renal or liver function and are taking colchicine.
- If you are pregnant, possibly 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 children aged 12 years or over and adults, take 3 tablets (375 mg of ensitrelvir) at a time, once a day on Day 1 and one tablet (125 mg) at a time, once a day from Days 2 to 5. Strictly follow the instructions.
- If you miss a dose, consult with your doctor, pharmacist or nurse. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor, pharmacist or nurse.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- If you are breastfeeding, it is recommended to avoid breastfeeding while taking this medicine and for 2 weeks after the last dose of this medicine.
- If you have a possibility of pregnancy, avoid pregnancy with your partner while taking this medicine and within 2 weeks after the last dose of this medicine.
- Avoid taking any food containing St. John's wort (a kind of herb), since it may diminish medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash and nausea. 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.

- generalised itching, hives, itchy throat, dizziness, palpitations, breathing difficulty [anaphylaxis]

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 the medicine out of the reach of infants and children. Store it 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, consult your pharmacy or medical institution about how to discard them. Do not give this medicine to anyone else.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.