

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

Internal

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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:ORLADEYO Capsules 150mg

Active ingredient:Berotralstat hydrochloride

Dosage form:blue/white capsule, major axis: approx. 19 mm, No. 1 capsule

Imprint or print on wrapping:オラデオカプセル 150mg, orladeyo 150mg



Effects of this medicine

This medicine inhibits the action of plasma kallikrein to suppress the onset of acute attack of hereditary angioedema (sudden swelling or edema that occurs in any part of the body).

It is usually used to suppress the onset of acute attack of hereditary angioedema.

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 or have a history of QT prolongation on electrocardiogram.
- If you are predisposed to develop QT prolongation (patients with arrhythmia, ischemic heart disease, hypokalemia, etc.).
- If you have liver disorder.
- 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 and children aged 12 years or older, take 1 capsule (150 mg as berotralstat) at a time, once a day. Strictly follow the instructions.
- Not for rescue treatment of acute attacks.
- 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 continue your regular dosing schedule. You should not 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include abdominal pain, diarrhea and abdominal bloating due to gas accumulation. 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.

- palpitation, fainting [QT prolongation (abnormal electrocardiogram)]
- general malaise, loss of appetite, nausea/vomiting [hepatic dysfunction]

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.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.