

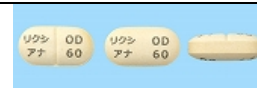
Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 01/2023

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:LIXIANA OD TABLETS 60 mg [treatment and prevention of recurrence of venous thromboembolism (deep venous thrombosis and pulmonary thromboembolism)]



Active ingredient:Edoxaban tosilate hydrate

Dosage form:faintly yellowish white tablet, major axis:13.4 mm, minor axis:7.0 mm, thickness: approximately 4.7 mm

Imprint or print on wrapping:リクシアナ OD 60mg, OD, Lixiana OD60mg, 経口 FXa 阻害剤, 口腔内崩壊錠

Effects of this medicine

This medicine suppresses blood coagulation by inhibiting activated blood coagulation factor X in the coagulation pathway. It suppresses blood coagulation, improves blood coagulation tendency, and prevents or treats disease (thromboembolism) caused by blood coagulation in blood vessels.

It is usually used for treatment and prevention of the recurrence of venous thromboembolism (deep venous thrombosis and pulmonary thromboembolism).

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: bleeding (intracranial bleeding, retroperitoneal bleeding or bleeding in other critical organs), bleeding tendency (bleeding disorders, gastrointestinal ulcers, diabetic retinopathy, cancer, anemia, etc.), acute bacterial endocarditis, renal failure, liver dysfunction or liver disease with coagulation disorder.
- If your body weight is less than 40 kg.
- 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 with body weight of 60 kg or less, take 30 mg of edoxaban at a time, once a day. For adults with body weight of more than 60 kg, take 60 mg of edoxaban at a time, once a day. The dosage may be decreased to 30 mg of edoxaban at a time, once a day according to your renal function and concomitant medications. This medicine contains 60 mg of edoxaban in a tablet. Strictly follow the instructions.
- Since this medicine dissolves in saliva when you place it on your tongue, you can take it without water. You can also take it with water.
- Do not take this medicine without water when you are lying down.
- 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. There should be 12 hours or more before the next scheduled dose. 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

- If nasal bleeding, gum bleeding, bruise, bloody urine, vomiting of blood or bloody stool occur, contact your doctor immediately.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include anemia, nasal bleeding, subcutaneous bleeding, bloody urine, contusion and wound haemorrhage. 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.

- vomiting of blood, black/bloody stool, stomachache [gastrointestinal bleeding]
- sudden headache, nausea, dizziness, motor paralysis, impaired consciousness [intracranial bleeding]
- bleary vision, visual impairment [intraocular bleeding]
- general malaise, loss of appetite, yellowing of the skin or white eyes [liver dysfunction, jaundice]

- bloody phlegm, dry cough, shortness of breath, breathing difficulty, fever [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. If you do not know how to discard the remainder, ask your pharmacist or medical institution. Do not give the medicine to anyone else.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.