

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

Internal

Revised: 02/2022

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:Xarelto Tablets 10mg [prevention of onset of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation]

Active ingredient:Rivaroxaban

Dosage form:pale red tablet, diameter: 6 mm, thickness: 2.8 mm

Imprint or print on wrapping:(face) イグザレルト 10mg, ▽10 (back) Xarelto 10mg



Effects of this medicine

This medicine inhibits blood coagulation factor Xa to prevent blood clotting. It improves clotting tendency in the atrium and prevents thromboembolism, a disease caused by blood coagulation in the vessels.

It is usually used to prevent onset of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

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, gastrointestinal bleeding, etc.), liver disorder, renal disorder, acute bacterial endocarditis or low body weight.
- If you are at high risk of bleeding (If you have recently had gastrointestinal tract ulcer, intracranial bleeding or cerebrospinal/eye surgery. If you have a history of bronchiectasis or lung bleeding. If you have gastric ulcer, duodenal ulcer, malignant tumor, coagulation disorder or haemostatic disorder).
- 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 adults, take 15 mg of the active ingredient at a time, once a day after meal. If you have renal disorder, the dosage will be decreased to 10 mg at a time, once a day. This preparation contains 10 mg of the active ingredient in a tablet. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, 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 you are receiving dental treatment, endoscopic examination or surgery, make sure to inform your doctor in advance that you are taking this medicine. If you are receiving treatment at other medical institutions or buying other medicines at pharmacies, etc., inform your doctor or pharmacist that you are taking this medicine.
- Pay attention not to get injured since this medicine lead to prolonged bleeding. If bleeding time is prolonged or the injury involves a large area, immediately contact your doctor.
- Refrain from taking any food containing hypericum perforatum (St. John's wort), since it may diminish medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nasal bleeding, gum bleeding, conjunctival bleeding, bloody urine, anemia and contusion. 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.

- nausea, vomiting, headache [bleeding (gastrointestinal bleeding, intracranial bleeding, etc.)]
- nausea, general malaise, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- dry cough, bloody phlegm, breathing difficulty, shortness of breath, fever [interstitial lung disease]
- nasal bleeding, gum bleeding, bruise, prolonged bleeding [decreased platelets]

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.