

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

Internal

Revised: 07/2016

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: Eliquis tablets 5 mg [prevention of onset of ischemic stroke and systemic embolism in patients with non-valvular atrial fibrillation]

Active ingredient: Apixaban

Dosage form: pink tablet, major axis: 9.7 mm, minor axis: 5.2 mm, thickness: 3.8 mm, weight: 208 mg

Imprint or print on wrapping: (Face) BMS Pfizer 5, 894 (Back) エリキュース 5 mg



Effects of this medicine

This medicine inhibits Factor Xa as the convergence point of the extrinsic and intrinsic blood coagulation pathways, resulting in the prevention of the conversion from prothrombin to thrombin further downstream, and shows direct anti-coagulant effects and indirect anti-platelet effects.

It is usually used to prevent the development 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 symptoms.
- If you have abnormal blood clotting.
- If you have liver disease with a risk of bleeding.
- If you have renal failure.
- If you are scheduled to receive a surgery.
- 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 5 mg of the active ingredient at a time twice a day. The dose may be reduced to 2.5 mg at a time twice a day according to your age, weight and renal function. Each tablet contains 5 mg of the active ingredient. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible, then take the medicine twice a day as usual. 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

- Take extra care when participating in exercise or work associated with a risk of injury and brush your teeth and blow your nose gently to prevent bleeding.
- Do not take Saint Johns Wort since it may diminish the effect of the medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nasal bleeding, bloody urine, contusion, hematoma and anemia. 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, dizziness, headache [intracranial bleeding]
- hematemesis, diarrhea, bloody stool [gastrointestinal bleeding]
- foggy vision, vision disorder [intraocular bleeding]
- cough, breathing difficulty, fever [interstitial lung disease]
- nausea, dull [liver 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.