

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

Internal

Revised: 09/2017

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: Warfarin Tablets 0.5mg

Active ingredient: Warfarin potassium

Dosage form: light yellow tablet (diameter: 7.6 mm, thickness: 2.8 mm)

Imprint or print on wrapping: ワーファリン 0.5mg, E255, Warfarin 0.5mg, ワーファリン, 0.5



Effects of this medicine

This medicine suppresses the function of vitamin K to inhibit blood clotting, and prevents a blood clot from forming. It is usually used in the treatment and prevention of venous thrombosis, myocardial infarction, pulmonary embolism, cerebral embolism, cerebral thrombosis etc.

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 reaction (itch, rash etc.) to any medicines or foods.
If you are taking capecitabine (Xeloda).
- If you are bleeding or prone to bleeding.
If you have: hepatic disorder, renal disorder, malignant tumor, hyperthyroidism, or hypothyroidism.
- If you are immediately after undergoing a surgery, getting an injury, labor or miscarriage.
- 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, the daily dosage will be determined by your doctor according to the findings of a blood coagulation test (prothrombin time, thrombotest and INR) etc.
The daily dosage for children will be also determined by your doctor according to the findings of a blood coagulation test. For infants under the age of 12 months: a standard of the maintenance dosage is 0.16 mg/kg/day. For children aged between 1 to under 15: a standard of the maintenance dosage is 0.04 to 0.10 mg/kg/day.
Strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible. However, if 12 hours or more has already passed since the scheduled time, skip the missed dose and continue your regular dosing schedule. 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

- Do not take foods and drinks containing vitamin K in large amount such as natto (fermented soybeans), chlorella, aojiru (green juice), and Saint John's Wort, since they may diminish the effect of the medicine.
- Drinking alcohol may influence the effect of the medicine. Avoid drinking an excessive amount of alcohol while you are receiving the medicine.
- The medicine has an action to prevent stopping bleeding. Avoid working or exercising which may lead to get injured.
- Keep the appointment with your doctor and take a blood coagulation test regularly. If you need to undergo a surgery or tooth extraction, consult with your doctor beforehand. If you need to be seen in another medical facility, tell the doctor, dentist or pharmacist in the facility that you are taking the medicine.
- The medicine has harmful effects to unborn babies. Avoid getting pregnant while you are receiving the medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, pruritus, erythema, hives, dermatitis, fever and hair loss. 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.

- headache, chest pain, abdominal pain, black stool, hematochezia, hematuria, gum bleeding, subcutaneous hemorrhage [intraorgan hemorrhage such as cerebral hemorrhage, mucosal hemorrhage, subcutaneous hemorrhage]
- flat red rash with pain, petechial hemorrhage, hemorrhagic blister [skin necrosis]

- painful skin ulcers, painful bruises [calciophylaxis]
- nausea, vomiting, loss of appetite, yellowing in the skin or conjunctiva ocular [hepatic dysfunction, jaundice]

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 children. Store it away from light, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.