

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

Internal

Revised: 07/2015

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: Digoxin-KY tablets 0.25

Active ingredient: Digoxin

Dosage form: white tablet (major axis: 7.8 mm, minor axis: 6.3 mm, thickness: 2.3 mm)

Print on wrapping: (face) KYO272, ジゴキシﾝ KY, 0.25mg, ジギタリス製剤
(back) ジゴキシﾝ KY, 0.25 mg, ジギタリス製剤



Effects of this medicine

This medicine strengthens myocardial contractile force, slows heart rate, and stabilizes pulse. It is usually used for the treatment of heart failure and tachycardia.

Before 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. If you have: heart disease, renal dysfunction, hypothyroidism, hyperthyroidism, or an electrolyte abnormality (including potassium, calcium or magnesium, etc.).
- If you are a hemodialytic patient.
- 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 >>
 - **For adults:** In general, as maintenance treatment, take 1 to 2 tablets (0.25 to 0.5 mg of the active ingredient) per day. [For rapid digitalization, for which the saturation dose with digoxin is 1.0 to 4.0 mg, take 0.5 to 1.0 mg initially followed by 0.5 mg every 6 to 8 hours until a sufficient response is observed.]
 - **For children:** In general, as maintenance treatment, give one-fifth to one-third of the saturation dose. [For rapid digitalization, give 0.06 to 0.08 mg/kg per day for a child 2 years old or younger and 0.04 to 0.06 mg/kg per day for a child 2 years old or older in 3 or 4 divided doses.]
- Each tablet contains 0.25 mg of the active ingredient. Strictly follow the instructions.
- If you miss a dose, skip the missed dose and take your next dose at the regular time. 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

- Due to the variation in optimal dosage of this medicine among individuals, your doctor may change your dose based on your condition. Therefore, contact your doctor routinely.
- DO NOT take health foods containing hypericum perforatum (St. John's wort); this may weaken the effect of this medicine by accelerating its metabolism. Consult with your doctor or pharmacist if you have taken such health foods.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, hives, purpura and edema. 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.

- loss of appetite, vomiting, visual abnormality, confusion, arrhythmia [digitalis toxicity]
- severe abdominal pain, bloody stools [non-occlusive mesenteric ischemia]

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 heat, moisture and light.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution when you discard the medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.