

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

Internal

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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: Rythmodan 50mg Capsules

Active ingredient: Disopyramide

Dosage form: Green/light green capsule, major axis: 14.00 mm, minor axis: 5.33 mm

Imprint or print on wrapping: RURH, リスモダン 50



Effects of this medicine

This medicine acts on heart, suppresses abnormal cardiac excitation and controls irregular pulse.

It is usually used to treat extrasystole, paroxysmal supraventricular tachycardia and atrial fibrillation when other anti-arrhythmic medications cannot be used or have no efficacy.

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 congestive heart failure, glaucoma, prone to urinary retention (difficulty urinating), heart disease (such as myocardial infarction, valvular disease or cardiac myopathy), conduction disturbance (such as atrioventricular, sinoatrial or bundle branch block), atrial flutter, diabetes mellitus, myasthenia gravis, or decreased serum potassium level.
- 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 2 capsules (100 mg as active ingredient) at a time, 3 times a day. The dosage may be adjusted according to the symptoms. Strictly follow the instructions.
- If you miss a dose, and if you have about 4 hours interval for the next dose, take the missed dose as soon as possible. If it is less than about 2 to 3 hours interval for the next dose, skip the missed 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

- You need to take tests (such as electrocardiography, pulse, blood pressure, cardiothoracic ratio and blood test) regularly. Make sure that you comply with the dates of visits.
- Serious hypoglycemia (initial symptoms: lassitude/malaise, hunger and cold sweat) may occur in elderly patients, patients with diabetes mellitus, liver disorder or renal disorder including on dialysis, or patients with poor nutrition. Make sure to inform your family and people around you that you are taking this medicine because this medicine may also cause consciousness disorder. You and your family also need to receive explanations until you gain sufficient understanding regarding hypoglycemia onset. If you have hypoglycemic symptoms and do not have consciousness disorder, take sugar in general. If you take this medicine concomitantly with an alfa-glucosidase inhibitor, take glucose. If you start having decreased consciousness, contact your doctor.
- This medicine may cause dizziness and hypoglycemia. Pay attention when working at heights or operating dangerous machinery, such as driving a car.
- Do not intake foods containing Saint John's wort with this medicine, since it may weaken the effect of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dry mouth, urination disorder (especially in elderly male), bradycardia, dizziness, headache, rash and vision disturbance. 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.

- shortness of breath, loss of consciousness, dizziness [cardiac arrest, ventricular fibrillation, ventricular tachycardia, ventricular flutter, atrial flutter, atrioventricular block, sinus arrest, syncope, aggravation of heart failure]
- fever, sore throat, muscle pain [agranulocytosis]
- yellow discoloration of skin and the white of eyes, general malaise, loss of appetite [liver dysfunction, jaundice]
- vomiting, severe abdominal pain, stoppage of defecation/passage of flatus [paralytic ileus]

- reduced visual acuity, nausea, eye pain/headache [worsening of glaucoma]

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, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.