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

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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 R 150mg Tablets |
| Active ingredient:Disopyramide phosphate Dosage form:white to faintly yellowish white tablet, diameter: 10.1 mm, thickness: 4.15 mm |
| Imprint or print on wrapping:リスモダン R 錠 150mg |
| Effects of this medicine |
| This medicine acts on heart, suppresses abnormal cardiac excitation and controls irregular pulse. |
| It is usually used to treat tachyarrhythmia 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, etc.), renal or liver |
| dysfunction, 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 1 tablet (150 mg as disopyramide) at a time, twice a day. The dosage may be adjusted |
| according to the age/symptoms. Strictly follow the instructions. |
| •Swallow the tablet without chewing, as this medicine is a sustained-release preparation. |
| • If you miss a dose, take the missed dose as soon as you remember. However, if it is almost time for the next dose, |
| skip the missed dose and follow 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 |
| •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, renal or liver dysfunction, or patients with poor nutrition. Make sure to inform your |
| family and people around you that you are taking this medicine, as 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 hypoglycemic symptoms. 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. |
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| 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 broath loss of consciousness dizziness [cardiac arrest ventricular fibrillation ventricular tachycardia |

• 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

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 $\boldsymbol{\cdot} \mathrm{Keep}$ 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, consult your pharmacy or medical institution about how to discard them. Do not give this medicine to others.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.