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: PROPAFENONE HYDROCHLORIDE TABLETS 100mg FOHARA I

Active ingredient:Propafenone hydrochloride

Dosage form: white tablet, diameter: 7.1 mm, thickness: 3.5 mm

Print on wrapping:プロパフェノン塩酸塩 100 mg「オーハラ」, プロパフェノン, 100 mg,

OH-140, 不整脈治療剤, Propafenone Hydrochloride100 mg

「OHARA」



Effects of this medicine

This medicine prolongs action potential duration by suppressing myocardial sodium channel activity and restores heart rhythm to normal.

It is usually used to treat tachyarrhythmia.

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 congestive heart failure or atrioventricular or sinoatrial block.
- · 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 150 mg of the active ingredient at a time, 3 times a day. The dosage may be adjusted according to your age/symptoms. Strictly follow the instructions.
- •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

- •Avoid taking any food containing St. John's wort (a kind of herb) with the medicine, since it may diminish medicinal effects.
- •This medicine may cause dizziness, etc., pay attention when operating dangerous machinery, such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dizziness/light headedness, palpitation, chest pain, jaundice, dull, rash and itch. 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.

- •palpitation, chest pain, dizziness [ventricular tachycardia, ventricular fibrillation, sinus arrest, sinoatrial block, atrioventricular block, bradycardia, syncope]
- •nausea, loss of appetite, dull [liver 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 out of the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Ask the pharmacy or medical institution on how to discard them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.

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