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

Internal

Revised: 12/2015

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: SARPOGRELATE HYDROCHLORIDE TABLETS 50mg "OHARA"

Active ingredient: Sarpogrelate hydrochloride

Dosage form: white tablet, diameter: 7.6 mm, thickness: 3.6 mm

Print on wrapping:サルポグレラート塩酸塩錠 50mg「オーハラ」, サルポグレラート塩酸

塩「オーハラ」, 50mg, OH-306, Sarpogrelate hydrochloride 50mg

「OHARA」



Effects of this medicine

This medicine inhibits serotonin receptor binding in platelet and vascular smooth muscle to control platelet aggregation and vasoconstriction. It interferes with the blood's ability to clot and consequently improves blood flow. It is usually used in the treatment of ulcer and improvement of the ischemic symptoms such as pain and coldness associated with chronic arterial obstruction.

Before using this medicine, be sure to tell your doctor and pharmacist

•If you ever experienced any allergic reaction (itch, rash etc.) to any medicine.

If you are bleeding (hemophilia, capillary fragility, gastrointestinal ulcer, urinary tract hemorrhage, hemoptysis, vitreous hemorrhage, etc.).

If you are a patient with renal disorder.

- · If you are pregnant, possibly 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 tablets (100 mg of the active ingredient) at a time, 3 times daily, after meal. The dosage may be adjusted according to the age or symptoms. Strictly follow the instructions of your doctor/pharmacist.
- If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. DO NOT take double doses to make up for the missed dose.
- ·If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop taking the medicine without the instructions of your doctor.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, heartburn, abdominal pain, rash, redness, papule, itch, erythema and hives. 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, nausea, vomiting blood, melena [intracerebral hemorrhage, gastrointestinal hemorrhage]
- •nasal bleeding, gum bleeding, subcutaneous hemorrhage in the limbs [thrombocytopenia]
- •general malaise, loss of appetite, yellowing in the skin and white of the eyes [hepatic dysfunction, jaundice]
- •throat pain, headache, fever with coldness and shivering [agranulocytosis]

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 direct sunlight, heat and moisture.
- •Do not store the remainder and discard it.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.

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