

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

Internal

Revised: 07/2023

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: ROSUVASTATIN TABLETS 5mg 「OHARA」

Active ingredient: Rosuvastatin calcium

Dosage form: light reddish yellow to smoky reddish yellow tablet, diameter: 7.0 mm, thickness: 3.9 mm

Imprint or print on wrapping: ロスバスタチン 5mg「オーハラ」, 高コレステロール血症のお薬です, 1日1回服用, Rosuvastatin 5mg「OHARA」



Effects of this medicine

This medicine selectively and competitively inhibits the activity of HMG-CoA reductase involving in cholesterol synthesis in liver. It consequently inhibits cholesterol synthesis and reduces cholesterol level in blood.

It is usually used to treat hypercholesterolemia or familial hypercholesterolemia.

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 liver/renal disease.
- 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, start taking 2.5 mg as rosuvastatin at a time, once a day. If you need to reduce LDL-cholesterol level promptly, the initial dose may be started with 1 tablet (5 mg) at a time. The dosage may be adjusted according to your age and symptoms. If it does not show enough efficacy after 4 weeks from the start, the dose may be increased. The maximum daily dose is 4 tablets (20 mg). This preparation contains 5 mg of the active ingredient in a tablet. Strictly follow the instructions.
- 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. 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

- Strictly follow the instructions on dietary/exercise therapy.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include muscle pain, itch, rash 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.

- muscle pain, losing strength in limbs, reddish brown urine [rhabdomyolysis, myopathy, immune-mediated necrotizing myopathy]
- malaise, loss of appetite, yellowing of the skin and the white of eyes [hepatitis, liver dysfunction, jaundice]
- nasal bleeding, gum bleeding, subcutaneous bleeding in limbs [decreased platelets]
- swelling of face/lips/eyelids, rash/itch, decreased consciousness [hypersensitivity]
- fever, dry cough, breathing difficulty [interstitial pneumonitis]

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 it at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of it, ask the pharmacy or medical institution on how to discard. Do not give it to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

SIE②