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

Internal
Revised: 12/2017

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: Crestor Tablets 2.5mg

Active ingredient: Rosuvastatin calcium

Dosage form: faintly-reddish pale yellow round tablet, diameter: approx. 5.5 mm, thickness: approx. 3.1 mm

Print on wrapping: (Face) クレストール 2.5mg, (Back) クレストール 2.5mg ZD4522

Effects of this medicine

This medicine selectively and competitively inhibits the activity of HMG-CoA reductase involving in cholesterol synthesis in liver, thereby inhibiting cholesterol synthesis and then reducing cholesterol level in blood.
It is usually used for the treatment of hypercholesterolemia or familial hypercholesterolemia.

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: liver disease or 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 1 tablet (2.5 mg as rosuvastatin) at a time, once a day. If you need to reduce LDL-cholesterol level promptly, your doctor may prescribe 2 tablets (5 mg) at a time, as an initial dose. The dosage may be adjusted according to your disease, age and symptoms. If it does not show enough efficacy after 4 weeks from the start, you may take higher dose and the dosage can be increased up to 8 tablets (20 mg) a day. Strictly follow the instructions.
- If you miss a dose, take it as soon as you remember. If it is close to your 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

- Follow your instructed dietary and/or exercise therapy properly.

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.

- pain in muscle, muscle weakness, lassitude, [rhabdomyolysis, myopathy, immune-mediated necrotizing myopathy]
- red-brown urine [rhabdomyolysis]
- loss of appetite, general dullness, yellowing of the skin/eyes [hepatitis, liver dysfunction, jaundice]
- nose bleeding, bleeding from gum, subcutaneous bleeding in limbs [thrombocytopenia]
- angioedema (swollen face/lips/eyelids), rash, itch, faint consciousness [hypersensitivity]
- fever, dry cough, respiratory distress [interstitial pneumonitis]
- hypoesthesia, numbness, muscle weakness in the limbs [peripheral neuropathy]
- fever, rash, blister [erythema multiforme]

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 infants and children. Store it at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.