

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

Internal

Revised: 05/2016

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:SIMVASTATIN TABLETS 20mg「OHARA」

Active ingredient:Simvastatin

Dosage form:white to yellowish white tablet (major axis: 14.0 mm, minor axis 7.5mm, thickness: 4.5 mm)

Print on wrapping:シンバスタチン 20mg「オーハラ」, OH-225, 20mg, Simvastatin20mg「OHARA」



Effects of this medicine

This medicine suppresses the function of cholesterol synthetase in the liver to lower cholesterol in the liver. This helps to take blood-cholesterol in the liver and consequently lowers blood-cholesterol.

It is usually used in the treatment of hyperlipidemia and 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 hepatic disorder or renal dysfunction.
- 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 5 mg of the active ingredient at a time, once daily. The dosage may be adjusted according to the age or symptoms, however, if lowering of LDL cholesterol level is insufficient, the dosage may be increased up to 1 tablet (20 mg) a day. This preparation contains 20mg of the active ingredient in a tablet. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible when you remember that you missed a dose. However, if it is almost time for the next dose, skip the missed dose and continue 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

- Strictly follow diet and exercise therapy instructed by your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, vomiting, rash, itch, muscle ache, malaise, abdominal pain, headache, constipation and diarrhea. 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 ache, feeling of weakness, reddish brown urine [rhabdomyolysis, myopathy]
- general malaise, loss of appetite, yellowing in the skin or white of the eye [hepatitis, hepatic dysfunction, jaundice]
- nasal bleeding, gum bleeding, subcutaneous bleeding in the limbs [thrombocytopenia]
- widespread redness, fever higher than thirty eight degree Celsius, general malaise [hypersensitivity syndrome]
- fever, dry cough, breathing difficulty [interstitial pneumonia]

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.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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