


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

610462016

Revised: 02/2011

<p>Information is based on approvals granted in Japan. In some cases, the approved details may vary in countries other than Japan. In deciding to use a medicine, the risk (side effects) of taking the medicine must be weighed against the benefit (effects) it will do. The patient's cooperation is indispensable here.</p>	
<p>Brand name : LIPOVAS Tablets - 20 Active ingredient : Simvastatin Dosage form : white tablet (major axis: 14.0 mm, minor axis: 7.5 mm, thickness: 4.6 mm) Printings on wrapping : リポバス 20, 20mg</p>	
<p>Effects of this medicine This medicine inhibits HMG-CoA reductase which is involved in biosynthesis of cholesterol, enhances LDL receptor activities in the liver, and consequently decreases cholesterol in blood. It is usually used in the treatment of hyperlipidemia and familial hypercholesterolemia.</p>	
<p>Before using this medicine, tell your doctor/pharmacist</p> <ul style="list-style-type: none"> • If you ever experienced any allergic reaction (itch, rash, etc.) to any medicine. If you are a patient with hepatic disorder, renal disorder, or hypothyroidism. If you or your family member have/has hereditary myopathy such as muscular dystrophy. • If you are pregnant or breastfeeding. • If you are using any other prescription or nonprescription (OTC) medicine. (It is important to reduce the risk of drug interactions.) 	
<p>Dosage regimen (proper use of this medicine)</p> <ul style="list-style-type: none"> • Your dosage regimen is: ◀◀ :order of your doctor>> • General dosage regimen: For adults, take 5 mg of the active ingredient at a time, once daily. The dosage may be adjusted according to the disease, age or symptoms, and if the effect is insufficient, it may be increased up to 20 mg daily. This preparation contains 20 mg of the active ingredient in a tablet. Strictly follow the instructions of your doctor/pharmacist. • Missed dose: Take a dose as soon as possible when you remembered 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. DO NOT take double doses to make up for the missed dose. • Overdose: If you took too much of the medicine (more than ordered), check with your doctor/pharmacist. • Others: Do not stop taking the medicine without the instructions of your doctor. 	
<p>Precautions while using this medicine</p> <ul style="list-style-type: none"> • Follow your doctor's instructions on the diet and exercise therapy. 	
<p>Side effects of this medicine Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: rash, itch, abdominal pain, nausea, vomiting, constipation, diarrhea, muscular pain, malaise, edema, headache, hepatic dysfunction, anemia, etc. In rare cases, symptoms described below may be the sign of side effects indicated in brackets []. If they occur, stop taking your medicine and check with your doctor immediately.</p> <ul style="list-style-type: none"> • muscular pain, weakness, reddish brown urine [rhabdomyolysis, myopathy] • general malaise, loss of appetite, yellowness in the skin or white of the eye [hepatitis, hepatic dysfunction, jaundice] • numbness in the limbs, hypesthesia [peripheral neuropathy] • bleeding tendency [thrombocytopenia] • fever, cough, breathing difficulty [interstitial pneumonia] <p>Other side effects not listed here may occur. Check with your doctor/pharmacist if you have any worrisome symptom.</p>	
<p>Storage and other information</p> <ul style="list-style-type: none"> • Keep the medicine out of the reach of children. Store it away from direct sunlight, heat and moisture. • Discard the remainder. Do not store them. 	

Continued on next page.

For doctor use only: Day Month Year

For further information, ask your doctor/pharmacist. Japanese package insert information (for medical professionals) is available on the website of Pharmaceuticals and Medical Devices Agency.