

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

Internal

Revised: 10/2016

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: Lipitor Tablets 5mg

Active ingredient: Atorvastatin calcium hydrate

Dosage form: very light pink tablet, diameter: 5.6mm, thickness: 2.7mm

Print on wrapping: (Face) リピトール 5mg, house-mark + 715, (Back) リピトール 5mg, house-mark



Effects of this medicine

This medicine prevents production of cholesterol in the liver, and thus lowers the cholesterol levels in the blood. It is usually used for the treatment of hypercholesterolaemia or familial hypercholesterolaemia.

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 or 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))
- For hypercholesterolaemia: In general for adults, take 2 tablets (10 mg of atorvastatin) at a time, once daily. The dosage may be adjusted according to the age or symptoms. For severe patients, the dosage may be increased up to a maximum dose of 4 tablets (20 mg) per day.
- For familial hypercholesterolaemia: In general for adults, take 2 tablets (10 mg of atorvastatin) at a time, once daily. The dosage may be adjusted according to the age or symptoms. For severe patients, the dosage may be increased up to a maximum dose of 8 tablets (40 mg) per day.
- In either case, strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible within before bedtime. 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.
- Intake of grapefruit juice may enhance the effect of this medicine. Refrain from taking the medicine together with grapefruit juice.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include stomach discomfort, itching, numbness of the fingers, loss of sleep, diarrhea, heartburn, constipation, headache and general malaise. 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, lassitude, reddish brown urine [rhabdomyolysis, myopathy, immune-mediated necrotizing myopathy]
- nausea/vomiting, general malaise, yellowing of the skin and the whites of the eyes [hepatitis fulminant, hepatitis, hepatic function disorder, jaundice]
- pharynx pain/headache/heaviness of the head, general malaise, bleeding of nose/gums or under the skin [agranulocytosis, pancytopenia, thrombocytopenia]
- fever, loss of appetite, red rash [oculomucocutaneous syndrome, toxic epidermal necrosis, erythema multiforme]
- dry mouth, excessive drinking/urination, getting tired easily [hyperglycaemia, diabetes mellitus]

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 infants and 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.