

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

Internal
Revised: 09/2020

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: LIVALO TABLETS 1mg**Active ingredient:** Pitavastatin calcium hydrate**Dosage form:** white tablet, diameter: 6.2 mm, thickness: 2.6 mm**Imprint or print on wrapping:** (Face) リバロ 1mg, 201, (Back) LIVALO 1mg, リバロ 1mg**Effects of this medicine**

This medicine inhibits HMG-CoA reductase to inhibit cholesterol synthesis in the liver, and consequently lowers cholesterol levels in the blood.

It is usually used in the treatment of hypercholesterolemia and 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 disorder, biliary atresia 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 the treatment of hypercholesterolemia: In general, for adults, take 1 to 2 tablets (1 to 2 mg of pitavastatin calcium) at a time, once a day. The dosage may be adjusted according to the age or symptoms. If lowering of LDL cholesterol level is insufficient, the dosage may be increased up to 4 tablets (4 mg) daily.
For the treatment of familial hypercholesterolemia: In general, for adults, take 1 to 2 tablets (1 to 2 mg of pitavastatin calcium) at a time, once a day. The dosage may be adjusted according to the age or symptoms. If lowering of LDL cholesterol level is insufficient, the dosage may be increased up to 4 tablets (4 mg) daily. In general, for children 10 years or older, take 1 tablet (1 mg) at a time, once a day. The dosage may be adjusted according to the symptoms. If lowering of LDL cholesterol level is insufficient, the dosage may be increased up to 2 tablets (2 mg) daily.
In any case, strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and follow 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 the instructions on dietary/exercise therapy.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itch, nausea, gastric distress, muscle pain, lassitude, headache/dull headache, numbness, dizziness, anemia and 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]
- muscle stiffness, pain, muscle weakness [myopathy, immune-mediated necrotizing myopathy]
- general malaise, nausea, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- nasal bleeding, gum bleeding, subcutaneous bleeding in the limbs [thrombocytopenia]
- fever, cough, respiratory distress [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 reach of children. Store away from light, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.