

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

Internal
Revised: 12/2010

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:Urso Tablets 100 mg

Active ingredient:Ursodeoxycholic acid

Dosage form:white tablets, φ 8.0 mm, thickness approx. 2.7 mm

Print on wrapping:ウルソ 100mg, URSO100mg



Effects of this medicine

This medicine increases bile secretion and thereby improves the bile flow. This medicine replaces hydrophobic bile acids in the liver, resulting in alleviation of hepatotoxicity. Moreover, this medicine inhibits cytokine/chemokine production and the infiltration of inflammatory cells into the liver, leading to improvement of liver dysfunction. In addition to these effects, this medicine provides dissolution of gallstones and improvement of digestion and absorption.

Usually, it is used to treat disease of biliary system and liver disease resulting from bile flow retention, improve dyspepsia after small intestine resection and that in inflammatory disease of small intestine, dissolve cholesterol gallstones, and improve liver function in chronic liver disease, primary biliary cirrhosis and chronic liver disease due to hepatitis C virus.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you ever experienced any allergic reaction (itch, rash etc.) to any medicine.
If you are patients with complete biliary obstruction and fulminant hepatitis.
- If you are 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>>
- General dosage regimen: For treatment of liver disease and improvement of liver function and dyspepsia, for adults, take 50 mg of the active ingredient at a time, three times a day. It should be adjusted according to your disease, age and symptom. One tablet contains 100 mg of the active ingredient. Strictly follow the instructions of your doctor/pharmacist.
For dissolution of cholesterol gallstones, for adults, take 2 tablets (200 mg of the active ingredient) at a time, three times a day. It should be adjusted according to your age and symptom. Strictly follow the instructions of your doctor/pharmacist.
For improvement of liver function in primary biliary cirrhosis and chronic liver disease due to hepatitis C virus, for adults, take 2 tablets (200 mg of the active ingredient) at a time, three times a day. It should be adjusted according to your disease age and symptom. The maximum daily dosage should be within 9 tablets (900 mg). Strictly follow the instructions of your doctor/pharmacist.
- If you are ordered to use the medicine on regular schedule and you missed a dose, take a dose as soon as possible.
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.
- If you took too much of the medicine (more than ordered), check with your doctor/pharmacist.
- Do not stop taking the medicine without the instructions of your doctor.

Precautions while taking this medicine

Possible adverse reactions to this medicine

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: diarrhea, loose stools, constipation, nausea, itching, urticaria, rash, erythema, etc.

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.

- fever, dry 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 the reach of children. Store away from heat, humidity and direct sunlight.
- If any medicine is left, do not store them. You must discard the remainder.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.