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Ursodiol

Ursodiol ⊲

Generic name: ursodiol [ur-so-DY-all]

Brand names: Reltone, Actigall, Urso, Urso DS, Urso Forte

Dosage forms: oral capsule (200 mg; 300 mg; 400 mg), oral tablet (250 mg; 500 mg)

Drug class: Gallstone solubilizing agents

Medically reviewed by Sanjai Sinha, MD. Last updated on Nov 20, 2024.

Uses Side effects Warnings Before taking Dosage Interactions

What is ursodiol?

Ursodiol capsules are used to dissolve small gallstones that cannot be removed with surgery, or to prevent gallstones that may occur during rapid weight loss. Ursodiol will not dissolve calcified gallstones.

Ursodiol tablets are used to treat primary biliary cirrhosis, an autoimmune disorder that causes progressive destruction of the bile ducts in your liver.

Ursodiol is also known as ursodeoxycholic acid.

Ursodiol may also be used for purposes not listed in this medication guide.

Ursodiol side effects

Get emergency medical help if you have **signs of an allergic reaction:** hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Ursodiol may cause serious side effects. Call your doctor at once if you have:

- pain or burning when you urinate;
- stomach pain or discomfort, constipation, vomiting;
- liver problems--nausea, upper stomach pain, itching, tired feeling, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes); or
- signs of a new infection--sudden weakness or ill feeling, fever, chills, sore throat, mouth sores, skin sores, trouble swallowing.

Common side effects of ursodiol may include:

• upset stomach, nausea, vomiting;

- diarrhea, constipation;
- cough, sore throat;
- · painful urination;
- hair loss; or
- back pain.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

1 Ursodiol side effects (more detail)

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Warnings

Use only as directed. Tell your doctor if you use other medicines or have other medical conditions or allergies.

Before taking this medicine

You should not use ursodiol if you are allergic to it, or if you have an obstruction in your liver or gallbladder.

Tell your doctor if:

• you have been coughing up blood; or

• you have gained weight rapidly, especially in your face and midsection.

Tell your doctor if you are pregnant or breastfeeding.

Not approved for use by anyone younger than 18 years old.

1 Ursodiol pregnancy and breastfeeding warnings (more detail)

How should I take ursodiol?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

Take the ursodiol tablet with food.

You may need to break a tablet in half to get your correct dose.

Swallow each tablet piece whole with a glass of water. A broken tablet may have a bitter taste.

After breaking a tablet, keep it separate from the whole tablets and use it within 28 days after breaking.

Use ursodiol regularly for the best results.

Doses are based on weight. Your dose may change if you gain or lose weight.

You may need medical tests, including gallbladder ultrasound exams and blood tests to check your liver function. You may also need liver function tests every 6 months after you stop using ursodiol.

Call your doctor if your symptoms do not improve, or if they get worse.

To treat gallstones, you may have to take ursodiol for several months. Some gallstones may not completely dissolve, and you may develop new gallstones within 5 years after treatment. Ask your doctor about your risk.

Store tightly closed at room temperature, away from moisture and heat.

Ursodiol dosing information

Usual Adult Dose for Biliary Cirrhosis:

Tablets: 13 to 15 mg/kg orally per day, given in 2 to 4 divided doses with food

Comments:

-The dose should be adjusted to the patient's needs.

-Scored tablets may be broken in half to provide recommended doses.

Use: Treatment of patients with primary biliary cirrhosis (PBC)

Usual Adult Dose for Gallbladder Disease:

Capsules:

Gallstone dissolution: 8 to 10 mg/kg orally per day, given in 2 to 3 divided doses

Gallstone prevention: 300 mg orally 2 times a day

-Maximum dose: 600 mg/day

Comments:

- -Safety in the dissolution of gallstones has not been established in patients using this drug beyond 24 months.
- -Ultrasound images should be obtained every 6 months for the first year.
- -If gallstones appear to have dissolved, treatment should be continued, and dissolution should be confirmed on a repeat ultrasound in 1 to 3 months.
- -Most patients who achieve complete dissolution show partial or complete dissolution at the first on-treatment reevaluation.
- -If partial stone dissolution is not observed after 12 months of treatment, the likelihood of treatment is significantly reduced.

Uses:

- -Patients with radiolucent, noncalcified gallbladder stones less than 20 mm in greatest diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to advanced age, idiosyncratic reaction to general anesthesia, systemic disease, or those who refuse surgery
- -For the prevention of gallstone formation in obese patients experiencing rapid weight loss



What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

Get your prescription refilled before you run out of medicine completely.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking ursodiol?

Ask your doctor before taking an antacid, and take only the type your doctor recommends.

What other drugs will affect ursodiol?

It may be harder for your body to absorb ursodiol if you take certain cholesterol-lowering medicines, such as:

- · antacids that contain aluminum;
- · cholestyramine; or
- · colestipol.

Tell your doctor about all your other medicines, especially birth control pills, clofibrate, and other estrogens.

Other drugs may affect ursodiol, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Ursodiol drug interactions (more detail)

Does ursodiol interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

ursodiol	
+	
Enter a drug name	Add

More about ursodiol

- · Check interactions
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Patient resources

Other brands

Actigall, Urso, Urso Forte

Professional resources

- Ursodiol monograph
- Ursodiol (FDA)
- Ursodiol Capsules (FDA)

Other brands

Related treatment guides

- · Primary Biliary Cholangitis
- Gallbladder Disease
- Nonalcoholic Steatohepatitis

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ন্ড Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

User Reviews & Ratings

8.0 / 10

32 Reviews

Images

Ursodiol 300 mg (E503 E503)



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