**URSETOR**

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only**

Abbreviated Prescribing information for URSETOR [Ursodeoxycholic Acid (Ursodiol) 600mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

**PHARMACOLOGICAL PROPERTIES**: Ursodeoxycholic acid, a naturally occurring bile acid found in small quantities in normal human bile and in the bile of certain other mammals. It suppresses hepatic synthesis and secretion of cholesterol, and also inhibits intestinal absorption of cholesterol.

**INDICATION:** Indicated for dissolution of small to medium sized radiolucent, noncalcified gallbladder stones <20 mm in greatest diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery. Safety of use of Ursodeoxycholic acid beyond 24 months is not established. It is also indicated for the prevention of gallstone formation in obese patients experiencing rapid weight loss.

**DOSAGE AND ADMINISTRATION:** The recommended dose for treatment of radiolucent gallbladder stones is 8-10 mg/kg/day given in 2 or 3 divided doses. If gallstones appear to have dissolved, Ursodeoxycholic acid therapy should be continued and dissolution confirmed on a repeat ultrasound examination within 1-3 months. **Gallstone Prevention:** The recommended dosage for gallstone prevention in patients undergoing rapid weight loss is 600 mg/day (300 mg twice a day).

**CONTRAINDICATION:** Not for patients with calcified cholesterol stones, radiopaque stones, or radiolucent bile pigment stones. Not for patients with compelling reasons for cholecystectomy including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula and for patients with allergy to bile acids.

**WARNINGS & PRECAUTIONS:** lithocholate (liver toxic metabolite) induced liver damage in patients with congenital or acquired deficiency in sulfation. Monitor the SGOT (AST) and SGPT (ALT) from the initiation of therapy and thereafter as per particular clinical circumstances.

**DRUG INTERACTIONS:** Interactions with bile acid sequestering agents such as cholestyramine and colestipol, albumin–based antacids, estrogens, oral contraceptives, and clofibrate (and perhaps other lipid lowering drugs) when administered concomitantly.

**ADVERSE REACTIONS:** Pasty stools or diarrhea, severe right upper abdominal pain, nausea, vomiting, calcification of gallstones, decompensation of hepatic cirrhosis, urticarial and pruritus.

**MARKETED BY:**

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(Additional information is available on request)