

URSETOR PLUS

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

Abbreviated Prescribing information for Ursetor Plus [Ursodeoxycholic acid 300mg and silymarin 140 mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Ursodeoxycholic acid** suppresses hepatic synthesis and secretion of cholesterol, and also inhibits intestinal absorption of cholesterol. It appears to have little inhibitory effect on synthesis and secretion into bile of endogenous bile acids, and does not appear to affect secretion of phospholipids into bile. **Silymarin's** hepatoprotective effects are accomplished via several mechanisms including antioxidation, inhibition of lipid peroxidation, and enhanced liver detoxification via inhibition of Phase I detoxification and enhanced glucuronidation, and protection of glutathione depletion.

INDICATION: It is indicated for patients for dissolution of small to medium sized radiolucent, non-calcified gallbladder stones <20mm 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. Ursodeoxycholic acid is indicated for the prevention of gallstone formation in obese patients experiencing rapid weight loss. Silymarin specially indicated in amanita mushroom poisoning, hepatitis, alcoholic liver disease and cirrhosis, hypercholesterolemia and psoriasis. Combination especially indicated in patients of gall bladder stone having predisposition or co-existing hepatic damage.

DOSAGE AND ADMINISTRATION: Combination can be given as one tablet 2-3 times a day as per physician advice.

CONTRAINDICATION: Contraindicated in patients with known hypersensitivity, compelling reasons for cholecystectomy including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula.

WARNINGS & PRECAUTIONS: Patients given Ursodeoxycholic acid should have SGOT (AST) and SGPT (ALT) measured at the initiation of therapy and thereafter as indicated by the particular clinical circumstances. Silymarin may lower blood sugar levels. Caution is advised in patients with diabetes or hypoglycemia, and in those taking drugs that affect blood sugar. Serum glucose levels may need to be monitored. Gallbladder stone dissolution with ursodeoxycholic acid treatment requires months of therapy. Complete dissolution does not occur in all patients and recurrence of stones within 5 years has been observed in up to 50% of patients who do dissolve their stones on bile acid therapy. Patients should be carefully selected for therapy with ursodeoxycholic acid, and alternative therapies should be considered.

DRUG INTERACTIONS: Cholestyramine, colestipol, aluminum-based antacids, estrogens, oral contraceptives and clofibrate. No drug interactions could be found with Silymarin.

ADVERSE REACTIONS: Ursodeoxycholic acid: Pasty stools or diarrhea, severe right upper abdominal pain, nausea, vomiting, decompensation of hepatic cirrhosis, urticarial and pruritus. **Silymarin:** laxative effect, bloating, dyspepsia, nausea, irregular stools, allergic reaction in some individuals, particularly those with known allergies to plants in the *Asteraceae* family (thistles, daisies, artichokes).

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/ URSETOR PLUS /Apr-2015/01/ABPI

(Additional information is available on request)