

Composition : Ursodeoxycholic Acid 150mg, 300mg Tablet & 250mg/5ml Suspension.

Indications : This drug is indicated for the dissolution of small to medium sized radiolucent, cholesterol rich gall-stones in functioning gall bladders. This drug is also indicated for the treatment of primary biliary cirrhosis.

Dosage & administration : Adults and Elderly : Dissolution of gallstones : 8-12mg/kg body weight daily as a single dose at bedtime or in two divided doses, for up to 2 years; treatment is continued for 3-4 months after stones dissolve. The following dosage regimen is recommended for suspension :

Body weight (kg)	Spoonfuls (5ml) (in 2-4 divided doses)	mg/kg/day
50-62	2	8.1-10.0
63-85	3	8.8-11.9
86-120	4	8.3-11.6

Prevention of gallstone formation: 300mg twice daily. **Primary biliary cirrhosis:** 10-15mg/kg body weight daily as a single dose or in 2-4 divided doses. The following dosage regimen is recommended for suspension :

Body weight (kg)	Spoonfuls (5ml) (in 2-4 divided doses)	mg/kg/day
50-62	2-4	10.0-16.1
63-85	3-5	11.9-14.7
86-120	4-7	11.6-14.6

Children : Not recommended. Or, as directed by the registered physician.

Contraindications : This medicine is contraindicated to radio-opaque calcified gall-stones, non-functioning gall bladder, inflammatory diseases and other

Ursolic

Tablet & Suspension

conditions of the small intestine, colon and liver which interfere with enterohepatic circulation of bile salts.

Side effects : This drug may give rise to nausea, vomiting, diarrhea, gallstone calcification and pruritus.

Precautions : Excessive dietary intake of calories and cholesterol should be avoided. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

Use in pregnancy and lactation : Pregnancy Category **B** by FDA.

Drug interaction : This drug should not be administered with oral contraceptives, oestrogenic hormones and other drugs which reduce the blood cholesterol level and increase the bile cholesterol level. Concomitant administration with bile acid binding drugs including antacids, charcoal and cholestyramine should be avoided, since this may reduce the effectiveness of therapy with Ursodeoxycholic acid.

Packing :

Ursolic 150 : 2x10's tablets in blister pack.

Ursolic 300 : 1x10's tablets in blister pack.

Ursolic Suspension : 50ml oral suspension.