URSODEX

URSODEOXYCOLIC ACID BP

Compositions:
Ursodex 150 Tablet: Each film-coated tablet contains Ursodeoxycholic Acid BP 150 mg. Ursodex 300 Tablet: Each film-coated tablet contains Ursodeoxycholic Acid BP 300 mg.

Pharmacology:
Ursodeoxycholic acid (Ursodex) reduces elevated liver enzyme levels by facilitating bile flow through the liver and protecting liver cells. The main mechanism if anticholelithic. Although the exact process of ursodiol's anticholelithic action is not completely understood, it is thought that the drug is concentrated in bile and decreases biliary cholesterol by suppressing hepatic synthesis and secretion of cholesterol and by inhibiting its intestinal absorption. The reduced cholesterol saturation permits the gradual solubilization of cholesterol from gallstones, resulting in their eventual dissolution.

Dosage And Administration:
Primary biliary cirrhosis: The recommended adult dosage for Ursodex in the treatment of PBC is 13-15 mg/kg/day administered in two to four divided doses with food. Dissolution of gallstones: The recommended adult dose is 6-12 mg/kg/day as a single dose at bedtime. Dosing regimen should be adjusted according to each patient's need at the discretion of the physician.

Contraindications:
Non-functioning gall-bladder calcified and pigmented gallstones, inflammatory bowel disease

Warning And Precaution:
Caution should be exercised in patients with history of liver, gallbladder, pancreas, or bile duct disorders, during pregnancy and breastfeeding.

Side Effects:
Diarrhoea, constipation, stomach upset, indigestion, dizziness, vomiting, cough, sore throat, runny nose, back pain, muscle and joint pain, hair loss.

Use in Pregnancy and Lactation:
PregnancyPregnancy Category-B. No evidence of harm has been reported in pregnancy. It has been effectively used for the treatment of cholestasis of pregnancy during the last trimester without any side effects. Lactation: Problems have not been documented in humans regarding breast feeding. So patients taking the drug during breast-feed to consults with doctors.

Drug Interaction:
Moderate interactions of ursodiol include: aluminum hydroxide calcium carbonate crofelemer eluxadoline ethinylestradiol sodium bicarbonate sodium citrate/citric acid

Overdosage:
50% of cases have stone recurrence in 5 years.

Storage:
Keep in a cool (below 30°C) and dry place, protected from light. Keep out of the reach of children.

Packing:
Ursodex-150 : Each box contains 4X10 Tablets in blister pack. Ursodex-300 : Each box contains 2 x 10 Tablets in blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.