

# Urso™

## Ursodeoxycholic Acid BP

### COMPOSITION

**Urso™ 150 Tablet:** Each film coated tablet contains Ursodeoxycholic Acid BP 150 mg.

**Urso™ 300 Tablet:** Each film coated tablet contains Ursodeoxycholic Acid BP 300 mg.

### PHARMACOLOGY

Ursodeoxycholic Acid is a naturally occurring bile acid used to treat different hepatobiliary disorders. The activity of Ursodeoxycholic Acid is achieved through a decrease in secretion of cholesterol in bile. Ursodeoxycholic Acid achieves this through a few mechanisms: it reduces cholesterol absorption, suppresses liver cholesterol synthesis and it does not inhibit bile acid synthesis. Therefore, alters bile composition from supersaturated to unsaturated.

Ursodeoxycholic Acid also promotes the formation of liquid cholesterol crystal complexes which enhance removal of the cholesterol from the gallbladder into the intestine to be expelled. Ursodeoxycholic Acid improves cholestatic liver diseases by-

- Protecting cholangiocytes against cytotoxicity of hydrophobic bile acids

- Stimulating hepatobiliary secretion

- Protecting hepatocytes against bile acid-induced apoptosis

Ursodeoxycholic Acid is completely absorbed in the upper intestine. Time to peak serum concentration varies from 30-150 minutes. The rate of absorption ranges from 60-80%. After absorption Ursodeoxycholic Acid enters the portal vein and undergoes extraction from portal blood by liver where it is conjugated with amino acid & that may be either glycine or taurine and then secreted into the hepatic bile ducts. Small quantities of Ursodeoxycholic Acid appear in the circulation and very small amounts are excreted into urine. The biologic half life of Ursodeoxycholic Acid ranges from 3.5-5.8 days.

### INDICATION

**Urso™** is indicated for the treatment of Cholestasis (Jaundice), Viral Hepatitis, Alcoholic Fatty Liver, Primary Biliary Cirrhosis (PBC), Primary Sclerosing Cholangitis (PSC), Dissolution of Gallstones and Non-Alcoholic Steato Hepatitis (NASH).

### DOSAGE AND ADMINISTRATION

The tablet should be taken for various disease purposes according to the following dosing table:

Disease	Dose
Dissolution of Gall stones	8-12 mg/kg/day either as single night time dose or in divided doses
PBC	10-15 mg/kg/day in 2-4 divided doses
Acute Viral Hepatitis	600 mg/day
Alcoholic Fatty Liver	300 mg/day
PSC	25-30 mg/kg/day
NASH	13-15 mg/kg/day

### USE IN PREGNANCY AND LACTATION

Pregnancy 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.

Problems have not been documented in humans regarding breast feeding.

### CONTRAINDICATION

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

### PRECAUTION AND WARNING

It should be used cautiously in those with liver disease.

### DRUG INTERACTION

Ursodeoxycholic Acid should not be used with drugs, such as estrogenic hormones that increase bile cholesterol. 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.

### SIDE EFFECT

Nausea, vomiting, diarrhea, gallstones calcification and pruritus.

### STORAGE

Store below 25° C. Protected from light and moisture. Keep the medicine out of the reach of children.

### HOW SUPPLIED

**Urso™ 150 Tablet:** Each box contains 20 Tablets in blister pack.

**Urso™ 300 Tablet:** Each box contains 20 Tablets in blister pack.

Manufactured by



**SQUARE**  
**PHARMACEUTICALS LTD.**  
**BANGLADESH**