

# URSODIL

Ursodeoxycholic Acid Tablet

## Presentation

**Ursodil:** Each tablet contains Ursodeoxycholic acid BP 300 mg.

## Pharmacodynamics

When given by mouth, ursodeoxycholic acid reduces the ratio of cholesterol to bile salts plus phospholipids in bile, causing desaturation of cholesterol saturated bile. The exact mechanism of action has not been fully elucidated.

## Pharmacokinetics

Ursodeoxycholic acid is absorbed from the gastro-intestinal tract and undergoes first pass metabolism and enterohepatic recycling. It is partially conjugated in the liver before being excreted into bile and undergoing 7-?-dehydroxylation to lithocholic acid, some of which is excreted directly in the faeces. The rest is absorbed and mainly conjugated and sulphated by the liver before excretion in the faeces.

## Indication

- Dissolution of cholesterol gallstones
- Primary biliary cirrhosis
- Primary sclerosing cholangitis
- Morbid obesity

## Dosage and Administration

Dissolution of gallstones: 8-12 mg/kg daily as a single dose at bedtime or in two divided dose for up to 2 years; treatment is continued for 3-4 months after stones dissolve.

Primary biliary cirrhosis: 10-15 mg/kg daily in 2-4 divided doses.

## Adverse effects

Ursodil may give rise to nausea, vomiting, diarrhoea and pruritus. A calcified layer may develop on the surface of the stone making it unable to be dissolved by bile acid therapy, resulting in surgery for some patients.

## Pregnancy and lactation

This product should not be used during pregnancy or lactation. Measures should be taken to prevent pregnancy if given to women of childbearing age. A non-hormonal contraceptive should be used. Treatment should be discontinued immediately if pregnancy occurs and medical advice sought.

## Contraindications

1. Use in patients with radio-opaque calcified gall-stones, or in those with non-functioning gall bladders.
2. Use in women who may become pregnant.
3. Use in patients with chronic liver disease, peptic ulcers or in those with inflammatory diseases of the small intestine and colon.

## Overdose

Bile acids are removed in the faeces either unchanged or as bacterial metabolites. It is unlikely therefore that serious toxicity would occur following overdose. The most likely result is diarrhoea which should be treated symptomatically and supportively.

## Drug Interaction

Urdox tablets should not be administered with oral contraceptives, oestrogenic hormones and other drugs which reduce the blood cholesterol level and increase the bile cholesterol level. Antacids bind bile acids in the gut. Drugs such as charcoal, colestipol and cholestyramine bind bile acids in vitro. All the above should be avoided during bile acid therapy as they may limit the effectiveness of therapy. Ursodeoxycholic acid may increase the absorption and serum levels of ciclosporin in some patients.

## Storage

Store at a temperature not exceeding 30°C. Protect from direct sunlight. Keep out of reach of children.

## Shelf-life

Please refer to outer carton.

## Commercial Pack

Please refer to the outer carton.

Manufactured By :

 **GENERAL**  
Pharmaceuticals Ltd.  
Tetkoids, Mouchat, Kalokari, Gazipur, Bangladesh  
www.generalpharma.com



The information given here is limited. For further information consult your doctor or pharmacist.