

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

1.1 Product Name:

URSOLIC 300 (Ursodeoxycholic Acid Tablets BP)

1.2 Pharmaceutical Dosage Form:

Solid dosage form (Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each film-coated tablet contains:

Ursodeoxycholic Acid BP....300 mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM:

Visual description of finished product:

Brown colour, circular, biconvex film-coated tablet.

4. Clinical particulars:

4.1 Therapeutic indications:

Ursolic tablets are indicated in the treatment of primary biliary cirrhosis (PBC) and for the dissolution of small to medium-sized radiolucent, cholesterol-rich gallstones in patients with a functioning gallbladder.

Cholesterol stones coated with calcium or stones composed of bile pigments are not dissolved by ursodeoxycholic acid. Ursodeoxycholic acid has a particular place in the treatment of patients in whom surgery is contraindicated or who are anxious to avoid surgery.

Paediatric population

Hepatobiliary disorder associated with cystic fibrosis in children aged 6 years to less than 18 years.

4.2 Posology and method of administration

Ursolic tablets are for oral administration

To be taken with a drink of water.

Primary Biliary Cirrhosis

Adults and Elderly: 10 - 15mg ursodeoxycholic acid (UDCA) per kg per day in two to four divided doses.

Children: Dosage should be related to body weight.

Dissolution of gallstones

Adults and Elderly:

The usual dose is 6 - 12mg/kg/day either as a single night-time dose or in divided doses. This may be increased to 15mg/kg/day in obese patients, if necessary.

The duration of treatment may be up to two years, depending on the size of the stone(s), and should be continued for three months after the apparent dissolution of the stone(s).

Children: Dosage should be related to body weight.

Paediatric population

Children with cystic fibrosis aged 6 years to less than 18 years: 20 mg/kg/day in 2-3 divided doses, with further increase to 30 mg/kg/day if necessary.

4.3 CONTRA-INDICATIONS:

Ursodeoxycholic acid should not be used in patients:

1. with radiopaque calcified gallstones,
2. with acute inflammation of the gallbladder or biliary tract.
3. with occlusion of the biliary tract (occlusion of the common bile duct or a cystic duct)
4. with frequent episodes of biliary colic
5. with impaired contractility of the gallbladder
6. with hypersensitivity to bile acids or any excipient of the formulation
7. who are pregnant or breastfeeding, or in women who may become pregnant.
8. with chronic liver disease, peptic ulcers or in those with inflammatory diseases of the small intestine and colon.

Paediatric population

Unsuccessful portoenterostomy or without recovery of good bile flow in children with biliary atresia

4.4 Special warning and special precaution for use

Ursodeoxycholic acid should be taken under medical supervision.

During the first 3 months of treatment, the liver function parameters AST (SGOT), ALT (SGPT) and γ -GT should be monitored by the physician every 4 weeks, thereafter every 3 months. Apart from allowing for identification of responders and non-responders in patients being treated for primary biliary cirrhosis, this monitoring would also enable early detection of potential hepatic deterioration, particularly in patients with advanced stage primary biliary cirrhosis.

When used for the dissolution of cholesterol gallstones:

In order to assess therapeutic progress and for timely detection of any calcification of the gallstones, depending on stone size, the gall bladder should be visualised (oral cholecystography) with overview and occlusion views in standing and supine positions (ultrasound control) 6-10 months after the beginning of treatment.

If the gall bladder cannot be visualised on X-ray images, or in cases of calcified gallstones, impaired contractility of the gall bladder or frequent episodes of biliary colic, ursodeoxycholic acid should not be used.

When used for treatment of advanced stage of primary biliary cirrhosis:

In very rare cases decompensation of hepatic cirrhosis has been observed, which partially regressed after the treatment was discontinued.

If diarrhoea occurs, the dose must be reduced and in cases of persistent diarrhoea, the therapy should be discontinued.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with FPPs and other forms of interaction

Ursodeoxycholic acid should not be administered concomitantly with charcoal, colestyramine, colestipol or antacids containing aluminium hydroxide and/or smectite (aluminium oxide), because these preparations bind ursodeoxycholic

acid in the intestine and thereby inhibit its absorption and efficacy. Should the use of a preparation containing one of these substances be necessary, it must be taken at least 2 hours before or after ursodeoxycholic acid.

Ursodeoxycholic acid can increase the absorption of ciclosporin from the intestine. In patients receiving ciclosporin treatment, blood concentrations of this substance should therefore be checked by the physician and the ciclosporin dose adjusted if necessary.

In isolated cases ursodeoxycholic acid can reduce the absorption of ciprofloxacin. Ursodeoxycholic acid has been shown to reduce the plasma peak concentrations (C_{max}) and the area under the curve (AUC) of the calcium antagonist nitrendipine. An interaction with a reduction of the therapeutic effect of dapsone was also reported. These observations together with in vitro findings could indicate a potential for ursodeoxycholic acid to induce cytochrome P450 3A enzymes. Controlled clinical trials have shown, however, that ursodeoxycholic acid does not have a relevant inductive effect on cytochrome P450 3A enzymes.

Oral contraceptives, oestrogenic hormones and blood cholesterol lowering agents such as clofibrate may increase biliary lithiasis, which is a counter-effect to ursodeoxycholic acid used for dissolution of gallstones.

4.6 Pregnancy and Lactation:

There are no adequate data on the use of ursodeoxycholic acid, particularly in the first trimester of pregnancy. Animal studies have provided evidence of a teratogenic effect during the early phase of gestation. Ursodeoxycholic acid must not be used during pregnancy. Treatment should be discontinued immediately if pregnancy occurs and medical advice sought.

Women of childbearing potential should be treated only if they are using reliable contraception: non-hormonal or low-oestrogen oral contraceptive measures are recommended. However, in patients taking ursodeoxycholic acid for dissolution of gallstones, effective non-hormonal contraception should be used, since hormonal oral contraceptives may increase biliary lithiasis. The possibility of a pregnancy must be excluded before beginning treatment.

It is not known whether ursodeoxycholic acid passes into breast milk. Therefore,

ursodeoxycholic acid should not be taken during lactation. If treatment with ursodeoxycholic acid is necessary, breastfeeding must be discontinued.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

The evaluation of undesirable effects is based on the following frequency data: Very common ($\geq 1/10$), Common ($\geq 1/100$ to $< 1/10$), Uncommon ($\geq 1/1,000$ to $< 1/100$), Rare ($\geq 1/10,000$ to $< 1/1,000$), and Very rare / Not known ($< 1/10,000$ / cannot be estimated from available data)

Gastrointestinal disorders:

In clinical trials, reports of pasty stools or diarrhoea during ursodeoxycholic acid therapy were common.

Very rarely, severe right upper abdominal pain has occurred during the treatment of primary biliary cirrhosis.

Ursodeoxycholic acid may give rise to nausea and vomiting. The frequency of these effects is not known.

Hepatobiliary disorders:

During treatment with ursodeoxycholic acid, calcification of gallstones can occur in very rare cases, making them unable to be dissolved by bile acid therapy and resulting in surgery for some patients.

During therapy of the advanced stages of primary biliary cirrhosis, in very rare cases decompensation of hepatic cirrhosis has been observed, which partially regressed after the treatment was discontinued.

Skin and subcutaneous disorders:

Very rarely, urticaria can occur.

Ursodeoxycholic acid may give rise to pruritus. The frequency of this effect is not known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal

product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority pharmacovigilance reporting channels.

4.9 Overdose

Diarrhoea may occur in cases of overdose. In general, other symptoms of overdose are unlikely because the absorption of ursodeoxycholic acid decreases with increasing dose and therefore more is excreted with the faeces.

No specific counter-measures are necessary and the consequences of diarrhoea should be treated symptomatically with restoration of fluid and electrolyte balance.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

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.

Paediatric population

Cystic fibrosis

From clinical reports, long-term experience up to 10 years and more is available with UCDA treatment in paediatric patients suffering from cystic fibrosis-associated hepatobiliary disorders (CFAHD). There is evidence that treatment with UCDA can decrease bile duct proliferation, halt progression of histological damage and even reverse hepato-biliary changes if given at early stage of CFAHD. Treatment with UDCA should be started as soon as the diagnosis of CFAHD is made in order to optimize treatment effectiveness.

5.2 Pharmacokinetic properties

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- α -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.

6. Pharmaceutical particulars

6.1 List of excipients

Excipients	Specification
Microcrystalline Cellulose	BP
Pregelatinised Starch (Lycatab-C)	BP
Sodium Starch Glycol late	BP
Polyvinylpyrrolidone PVPK-30	BP
Sodium Lauryl Sulphate	BP
Starch (For Paste)	BP
Magnesium stearate	BP
Purified Water	BP
Instacoat Sol IC-S-6098 Brown	In-house
Dichloromethane	BP
Isopropyl alcohol	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a dry place, below 30°C. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

10 Tablets are packed in an Alu-PVC blister pack, and such blister is packed in a carton along with a pack insert.

6.6 Special precautions for disposal and other handling

Not Applicable

7. Marketing authorization holder

ALKEM LABORATORIES LIMITED,

Alkem House, “Devashish”, Senapati Bapat Marg, Lower Parel, Mumbai – 400 013, India.

Manufacturer:

ALKEM LABORATORIES LIMITED.

8. Marketing authorization number(s)

H2025/CTD9740/21366.

9. Date of first authorization/renewal of the authorization

8th October 2025.

10. Date of revision of the text

8th October 2025.