

Brand Name: URCOLIC-300

Composition: Ursodeoxycholic Acid tablet IP 300 mg

Dosage Form: Tablets

Category: Hepatoprotective / Bile Acid Derivative

Packaging Type: ALU-ALU

Packaging: 10 x 10

Brief Product Introduction:

URCOLIC-300, manufactured by **AstraEureka Pharmaceutical**, a reliable **manufacturer of Ursodeoxycholic Acid composition**, is a hepatoprotective agent designed to support liver health and treat various hepatobiliary disorders. Each film-coated tablet contains **Ursodeoxycholic Acid 300 mg**, a naturally occurring bile acid that helps dissolve cholesterol-rich gallstones and improve bile flow. URCOLIC-300 is commonly used in the management of primary biliary cholangitis (PBC), cholestatic liver disease, non-alcoholic fatty liver disease (NAFLD), and certain chronic liver disorders. It stabilizes hepatocyte membranes, reduces toxic bile salts, and protects liver cells from damage. The formulation offers high bioavailability and is well tolerated over long-term use. URCOLIC-300 helps improve liver enzyme profiles, slows disease progression, and enhances quality of life in patients with chronic liver conditions.

Composition:

Each film-coated tablet contains:

Ursodeoxycholic Acid IP.....300 mg

Excipients.....q.s.

Key Benefits:

1. Promotes bile flow and reduces cholestasis
2. Helps dissolve cholesterol-rich gallstones (non-calcified)
3. Reduces liver enzyme levels in chronic liver disease
4. Protects hepatocytes from bile acid-induced damage
5. Useful in NAFLD, PBC, and cholestatic liver diseases

Indications:

1. Primary biliary cholangitis (PBC)
2. Gallstone dissolution (radiolucent, cholesterol stones)
3. Chronic liver disease and cirrhosis
4. Non-alcoholic fatty liver disease (NAFLD)
5. Intrahepatic cholestasis of pregnancy (under supervision)
6. Cystic fibrosis-associated liver disease

Directions for Use:

1. To be taken orally with or after meals
2. Swallow the tablet whole with water; do not chew or crush
3. Follow the exact dosage and duration as prescribed by the physician

Dosage and Administration:

- **Adults:** 8–10 mg/kg/day in divided doses (typically 300–900 mg daily)
- **Gallstone dissolution:** 300 mg twice daily for 6–12 months
- **PBC or chronic liver disease:** Dose individualized by physician
- Regular monitoring of liver function is recommended during therapy

Safety Information:

1. Use under medical supervision only
2. Monitor liver enzymes periodically during long-term use
3. Avoid use in patients with calcified or pigment gallstones
4. Not recommended in advanced cirrhosis with hepatic decompensation

Mechanism of Action:

- Ursodeoxycholic Acid (UDCA) is a hydrophilic bile acid that replaces toxic endogenous bile acids, reducing their cytotoxic effects on liver cells.
- It improves bile flow in cholestatic conditions, stabilizes hepatocyte membranes, reduces immune-mediated liver injury, and enhances cholesterol solubility in bile, promoting gradual dissolution of cholesterol gallstones.
- UDCA also exhibits anti-apoptotic and anti-inflammatory properties, improving overall liver function and delaying disease progression in chronic liver disorders.

Contraindications:

1. Hypersensitivity to Ursodeoxycholic Acid
2. Non-functional gallbladder or calcified gallstones
3. Acute inflammation of the gallbladder or biliary tract
4. Complete biliary obstruction

Side Effects:

1. Mild diarrhea or soft stools
2. Nausea, abdominal discomfort
3. Rare: Pruritus, skin rash, elevated liver enzymes

Important Notice:

- Medication effectiveness may require several months
- Regular ultrasound monitoring is advised for gallstone dissolution
- Not effective for pigment or radiopaque stones
- Adherence to dosage schedule is essential for efficacy

Storage Condition:

1. Store below 25°C in a dry, cool place
2. Protect from direct sunlight and moisture
3. Keep out of reach of children

Packing Information:

- Each strip contains 10 film-coated tablets
- Packed in ALU-ALU strips, 10 x 10 tablets per box

