

Uriviga 600 SR Tablet

Ursodeoxycholic Acid (600mg) SR Tablet

Category: Hepatoprotective Agent / Bile Acid

Dosage Form: Sustained-Release (SR) Oral Tablet

Description:

Ursodeoxycholic Acid (600mg) SR Tablet is a bile acid derivative formulated in a sustained-release form for convenient once-daily dosing. It is used to manage liver and gallbladder disorders, particularly cholestatic liver diseases and the dissolution of cholesterol-rich gallstones. The sustained-release formulation ensures gradual absorption and prolonged action, improving therapeutic outcomes.

Composition:

- **Active Ingredient:** Ursodeoxycholic Acid – 600mg (Sustained Release)
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Indications:

1. **Primary Biliary Cholangitis (PBC):** Slows disease progression by improving liver function and reducing inflammation.
2. **Gallstone Dissolution:** Dissolves small, non-calcified cholesterol gallstones in patients not suitable for surgery.

3. **Chronic Cholestatic Liver Diseases:** Manages bile flow-related liver dysfunctions like primary sclerosing cholangitis.
 4. **Non-Alcoholic Fatty Liver Disease (NAFLD):** Protects the liver and improves liver enzyme profiles.
 5. **Cystic Fibrosis-Associated Liver Disease:** Enhances bile flow to minimize complications.
 6. **Drug-Induced Hepatotoxicity:** Supports recovery in cases of medication-induced liver damage.
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Mechanism of Action:

Ursodeoxycholic acid (UDCA) works by:

- **Reducing Cholesterol Saturation:** Lowers cholesterol secretion into bile, reducing gallstone formation and promoting the dissolution of cholesterol-rich stones.
 - **Cytoprotective Effects:** Protects hepatocytes by stabilizing cell membranes and reducing bile acid toxicity.
 - **Improving Bile Flow:** Enhances bile secretion, relieving cholestasis.
 - **Anti-Inflammatory Activity:** Reduces liver inflammation in chronic conditions.
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Dosage and Administration:

- **Adults:**
 - **Gallstone Dissolution:** 8-10 mg/kg/day, taken once daily

due to the sustained-release formulation.

- **Chronic Liver Disease: 13-15 mg/kg/day; typically, one 600mg tablet daily or as directed by a physician.**
- **Administration:**
 - Swallow the tablet whole with water.
 - Take with food to improve absorption and efficacy.

- **Long-term therapy requires periodic evaluation of liver enzymes and gallbladder condition.**

4. Elderly and Pediatric Patients:

- **Dosage adjustments may be necessary based on age and weight.**

5. Underlying Conditions:

- **Use cautiously in patients with severe hepatic or renal impairment.**

Contraindications:

- 1. Gallstones with High Calcium Content: UDCA is ineffective in calcified gallstones.**
- 2. Acute Gallbladder or Bile Duct Infections.**
- 3. Complete Bile Duct Obstruction: UDCA requires bile flow to be effective.**
- 4. Severe Hepatic or Renal Impairment.**
- 5. Hypersensitivity: Allergic reactions to Ursodeoxycholic Acid or excipients.**

Adverse Effects:

Common Side Effects:

- **Diarrhea or soft stools**
- **Nausea**
- **Abdominal discomfort**
- **Flatulence**

Serious Side Effects:

- **Allergic reactions (rash, swelling, difficulty breathing)**
- **Elevated liver enzymes (ALT, AST)**
- **Gallstone complications (pain, inflammation)**
- **Severe jaundice (yellowing of the skin/eyes)**

Precautions:

- 1. Regular Monitoring:**
 - **Liver function tests (LFTs) and imaging (e.g., ultrasound) are essential to evaluate treatment response and liver health.**
- 2. Pregnancy and Lactation:**
 - **Use cautiously; consult a healthcare provider for risk-benefit assessment.**
- 3. Prolonged Use:**

Drug Interactions:

- 1. Cholestyramine or Colestipol: Reduces UDCA absorption; take 2-4 hours apart.**
- 2. Aluminum-Based Antacids: May reduce UDCA's effectiveness.**
- 3. Ciclosporin: May increase ciclosporin blood levels; monitor closely.**

- 4. Estrogen or Oral Contraceptives:
May counteract UDCA's gallstone
dissolution effect.**
 - 5. Lipid-Lowering Drugs: Monitor
closely for potential interactions.**
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Storage Instructions:

- **Store below 25°C in a cool, dry place
away from direct sunlight.**
 - **Keep out of reach of children.**
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Key Points:

- **Ursodeoxycholic Acid (600mg) SR
Tablet is a hepatoprotective agent
designed for once-daily dosing,
improving compliance and
therapeutic outcomes.**
- **Effective for gallstone dissolution,
chronic liver conditions, and bile
flow disorders.**
- **Regular monitoring is critical for
safety and efficacy.**
- **Take with food for enhanced
absorption.**

Always use under medical supervision.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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