

Uriviga SR 450 Tablet

Ursodeoxycholic Acid (450mg) SR Tablet

Category: Bile Acid / Hepatoprotective

Dosage Form: Sustained-Release Tablet

Description:

Ursodeoxycholic Acid (450mg) SR is a hepatoprotective medication used primarily to manage liver diseases, particularly those involving bile acids and liver function. It is a naturally occurring bile acid found in small amounts in human bile, and it plays a key role in bile secretion and the regulation of cholesterol metabolism. The sustained-release (SR) formulation ensures prolonged action, enhancing the drug's effectiveness and patient compliance by reducing the frequency of dosing.

Ursodeoxycholic acid helps to improve liver function by reducing the concentration of toxic bile acids, promoting bile flow, and preventing liver cell damage. It is commonly used in the treatment of primary biliary cirrhosis (PBC), gallstones, and certain forms of cholestasis, where bile flow is impaired.

Composition (Per Tablet):

- Ursodeoxycholic Acid (450mg)
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Indications:

Ursodeoxycholic Acid (450mg) SR is indicated for:

1. Primary Biliary Cirrhosis (PBC):

- Treatment to improve liver function and reduce the progression of primary biliary cirrhosis by slowing the deterioration of liver tissue and enhancing bile flow.

2. Gallstones (Cholesterol Stones):

- Used as a non-surgical treatment for cholesterol gallstones in patients who are unable to undergo surgery. It helps to dissolve gallstones by reducing cholesterol secretion in bile.

3. Cholestasis:

- Treatment of cholestasis (reduced bile flow) in conditions like intrahepatic cholestasis of pregnancy and cholestatic liver diseases.

4. Liver Disorders:

- It is sometimes used off-label in various liver disorders to improve bile secretion and prevent liver damage caused by abnormal bile acids.
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Dosage and Administration:

• For Primary Biliary Cirrhosis (PBC):

- Initial dose: 150mg to 300mg daily, typically divided into two doses.
- Maintenance dose: After 2-4 weeks, the dose may be increased to 450mg to 900mg daily, depending on response.

• For Gallstones:

- 10mg/kg body weight daily, administered in divided doses.

• For Cholestasis:

- 150mg to 300mg daily, may be adjusted based on patient response.
 - **Administration:**
 - Take the tablet orally with or without food.
 - The sustained-release formulation is designed for once-daily dosing to maintain steady levels of the medication over time.
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Mechanism of Action:

Ursodeoxycholic Acid (UDCA) is a naturally occurring bile acid that works by:

- **Reducing Toxic Bile Acids:** UDCA replaces more toxic bile acids in the bile, helping to reduce liver damage.
 - **Improving Bile Flow:** It promotes bile secretion, aiding in the digestion of fats and the absorption of fat-soluble vitamins, and helps reduce cholestasis (bile flow obstruction).
 - **Cholesterol Dissolution:** It reduces cholesterol secretion in bile and promotes the dissolution of cholesterol gallstones by preventing the formation of excess cholesterol in the gallbladder.
 - **Anti-inflammatory Effects:** It has anti-inflammatory properties that help reduce liver inflammation and prevent further liver damage, especially in liver diseases like primary biliary cirrhosis.
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Contraindications:

Ursodeoxycholic Acid (450mg) SR should not be used in patients with:

- Hypersensitivity to ursodeoxycholic acid or any other ingredients in the formulation.
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- Complete biliary obstruction (lack of bile flow due to blockage).
 - Severe liver failure or decompensated liver cirrhosis (as the liver cannot process the drug properly).
 - Pregnancy (unless clearly necessary) or breastfeeding (should be used cautiously or avoided).
 - Gallbladder dysfunction when gallstones cannot be dissolved, or patients have other reasons for surgery.
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Warnings and Precautions:

1. Liver Function Monitoring:

- Liver enzymes should be monitored regularly, especially in patients with pre-existing liver disease. Adjustments may be needed if liver function deteriorates.

2. Gallstone Treatment:

- Not effective in patients with large gallstones or calcified stones.
- Gallbladder ultrasound should be used to monitor the resolution of stones. If stones fail to dissolve after an adequate trial, surgery may be required.

3. Pregnancy and Lactation:

- The use of ursodeoxycholic acid during pregnancy should only be done under strict medical supervision if the potential benefit justifies the potential risk. It is not recommended during breastfeeding unless necessary.

4. Dosage Adjustments:

- Renal or hepatic impairment may require dosage adjustments. Close monitoring is essential in patients with compromised kidney or liver function.
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Adverse Effects:

Common Side Effects:

- **Diarrhea or loose stools.**
- **Nausea or vomiting.**
- **Abdominal discomfort.**
- **Fatigue or weakness.**

Serious Side Effects:

- **Severe liver reactions, including jaundice and elevated liver enzymes.**
- **Allergic reactions such as rash, itching, fever, or swelling.**
- **Cholestasis (increased liver dysfunction and bile obstruction).**

Very Rare Side Effects:

- **Gallbladder-related complications.**
- **Kidney damage (renal failure in very rare instances, especially with pre-existing renal dysfunction).**

If any severe reactions such as difficulty breathing, swelling, or severe abdominal pain occur, discontinue the medication and seek immediate medical attention.

Drug Interactions:

- **Cholestyramine or colestipol:** These bile acid sequestrants can reduce the absorption of ursodeoxycholic acid. It is advisable to take ursodeoxycholic acid at least 1 hour before or 4 hours after these medications.
- **Cyclosporine:** Cyclosporine levels may be reduced by ursodeoxycholic acid. Monitoring and dose adjustment may be needed for immunosuppressive therapies.
- **Estrogens:** Long-term use of estrogen-containing medications (such as

contraceptives or hormone replacement therapy) can increase the cholesterol content in bile, potentially reducing the effectiveness of ursodeoxycholic acid in gallstone therapy.

- **Other Hepatotoxic Drugs:** Caution is advised when using other drugs with potential liver toxicity, as they may increase the risk of liver damage when taken with ursodeoxycholic acid.
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Storage Instructions:

- **Store at room temperature (15°C to 25°C).**
 - **Keep in the original packaging to protect from moisture and light.**
 - **Keep out of reach of children.**
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Key Points for Use:

- **Ursodeoxycholic Acid 450mg SR is beneficial for managing liver conditions like PBC, cholestasis, and cholesterol gallstones.**
- **The sustained-release formulation provides a convenient once-daily dose.**
- **Monitor liver function and gallstone resolution during treatment.**
- **Avoid in cases of severe liver disease, biliary obstruction, or large gallstones that cannot be dissolved.**

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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