# Information For the Use Ursodeoxycholic Acid (125mg/5ml)

## **Uriviga Suspension**

Ursodeoxycholic	Acid	(125	mg/5	ml)
Suspension				

 To improve bile flow and prevent liver damage associated with cystic fibrosis.

### **Description:**

Ursodeoxycholic Acid (125 mg/5 ml) suspension is a bile acid preparation used primarily for the treatment of cholestatic liver disorders and gallstone-related conditions. Ursodeoxycholic acid helps improve bile flow, protect liver cells, and dissolve cholesterol-rich gallstones. Its liquid form is especially suitable for pediatric and elderly patients or those with difficulty swallowing tablets.

## **Composition:**

Each 5 ml of suspension contains:

Ursodeoxycholic Acid: 125 mg

## **Indications:**

This suspension is indicated for:

- 1. Liver Disorders:
  - o Primary biliary cirrhosis (PBC).
  - o Chronic cholestatic liver diseases.
  - Primary sclerosing cholangitis (PSC).
- 2. Gallstone Disease:
  - Dissolution of small, cholesterolrich gallstones in patients who cannot undergo surgery.
- 3. Pediatric Use:
  - Biliary atresia and other cholestatic conditions in children.
- 4. Cystic Fibrosis:

#### **Mechanism of Action:**

Ursodeoxycholic Acid reduces the cholesterol content of bile by:

- Decreasing cholesterol synthesis in the liver.
- Reducing intestinal absorption of cholesterol.
- Increasing the solubility of cholesterol in bile, facilitating the dissolution of gallstones.

It also has a cytoprotective effect on liver cells and improves bile flow in cholestatic liver diseases.

## **Dosage and Administration:**

- Adults:
  - Dosage depends on the condition being treated. Typically, 10-15 mg/kg/day, divided into 2–3 doses.
- Pediatric Use:
  - 10-20 mg/kg/day in divided doses, or as directed by a physician.
- Administration:
  - Shake the bottle well before use.
  - Administer using a measuring cup or oral syringe to ensure accuracy.

#### **Side Effects:**

Common side effects:

- Nausea, vomiting, or diarrhea.
- Abdominal pain or indigestion.
- Mild rash or itching.

#### Rare but serious side effects:

- Severe liver enzyme elevation.
- Allergic reactions (e.g., swelling, difficulty breathing).

#### **Precautions:**

- 1. Liver function monitoring:
  - Regularly monitor liver enzymes during treatment.
- 2. Gallstone type:
  - Effective only for cholesterol-rich gallstones; not suitable for calcified stones or bile pigment stones.
- 3. Pregnancy and breastfeeding:
  - Use only if prescribed during pregnancy. Safety in breastfeeding is not well established.
- 4. Pediatric use:
  - Use under medical supervision for children.

#### **Contraindications:**

- Known hypersensitivity to Ursodeoxycholic Acid or any component of the suspension.
- Acute inflammation of the gallbladder or bile ducts.
- Complete biliary obstruction.
- Presence of calcified gallstones.
- Severe liver impairment or decompensated cirrhosis.

## **Drug Interactions:**

- Cholestyramine, colestipol, or antacids containing aluminum: May reduce the absorption of Ursodeoxycholic Acid.
- Ciclosporin: Dose adjustment may be needed due to altered absorption.
- Estrogens or oral contraceptives: May reduce the effectiveness of gallstone dissolution.

## **Storage Instructions:**

- Store at room temperature  $(15^{\circ}C-30^{\circ}C)$ .
- Protect from light and moisture.
- Keep the bottle tightly closed and out of reach of children.

Note: Use under medical supervision. Regular follow-ups and monitoring of liver function tests are essential during treatment. If symptoms worsen or if side effects occur, consult your healthcare provider immediately.

Manufactured in India for:



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