



Ursodeoxycholic Acid 300 mg Tablets

*Grip on **Liver** Protection*

### **Product Description:**

Each tablet contains

- Ursodeoxycholic acid 300 mg,

### **General Information:**

Ursodeoxycholic acid (UDCA), also known as ursodiol, is a naturally-occurring bile acid that constitutes a minor fraction of the human bile acid pool. UDCA was first approved by the FDA in 1987 for dissolution of gallstones and for primary biliary cirrhosis in 1996. UDCA works by replacing the hydrophobic or more toxic bile acids from the bile acid pool. Ursodeoxycholic acid (UDCA) is a secondary bile acid with cytoprotectant, immunomodulating, and choleretic effects. It reduces the cholesterol fraction of biliary lipids. UDCA inhibits the absorption of cholesterol in the intestine and the secretion of cholesterol into bile, decreasing biliary cholesterol saturation. UDCA increases bile acid flow and promotes the secretion of bile acids.

### **Mechanism of Action:**

- UDCA works by replacing more toxic bile acids, such as chenodeoxycholic acid, with itself, which is less harmful to liver cells.
- It helps reduce bile acid toxicity, reduces inflammation in the liver, and improves bile flow (cholestasis).
- UDCA can also promote liver cell regeneration and reduce the liver's inflammatory response.

### **Medical Uses:**

- **Primary Biliary Cholangitis (PBC):** UDCA is most commonly used in the treatment of PBC, a chronic liver disease where the bile ducts are damaged, leading to bile buildup and liver injury. UDCA helps to improve liver function by promoting the flow of bile and reducing liver damage.
- **Gallstones:** UDCA is sometimes used to dissolve certain types of cholesterol gallstones, especially in patients who are not candidates for surgery.
- **Non-Alcoholic Fatty Liver Disease (NAFLD):** There is some evidence that UDCA may be helpful in managing liver dysfunction associated with NAFLD, although its use in this context

is not as established as in PBC.

### **Indications:**

- Gallstones
- Jaundice
- Non-Alcoholic Liver Disease
- Cirrhosis
- Steatosis
- Chronic Hepatitis
- Cholestasis

### **Dosage and administration:**

The dosage recommendation for ursodeoxycholic acid (UDCA) can vary depending on the condition being treated. Here are some typical dosage guidelines for common uses:

#### **1. Primary Biliary Cholangitis (PBC):**

- Initial dose: 13-15 mg/kg/day divided into two to four doses.
- Maintenance dose: 13-15 mg/kg/day divided into two doses.

#### **2. Gallstone Dissolution:**

- 8-10 mg/kg/day in two to three divided doses.

#### **3. Primary Sclerosing Cholangitis (PSC):**

- Initial dose: 13-15 mg/kg/day divided into two to four doses.
- Maintenance dose: 13-15 mg/kg/day divided into two doses.

#### **4. Cholestatic Liver Diseases:**

- 13-15 mg/kg/day in two to four divided doses.
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### **When not to use?**

**(i) Allergy:** Avoid taking URSOGRIP, if you are allergic to it. Seek medical attention if you experience symptoms such as skin rash, hives (painful eruptions that itch and sting), itching/swelling (especially of the face/tongue/throat), breathing difficulty, etc.

**(ii) Presence of calcified gallstone:** URSOGRIP is not recommended for use if you have gallstones formed due to the deposition of calcium. This medicine may not be effective in such a condition.

**(iii) Inflammatory bowel disease:** Inflammatory bowel disease is a group of conditions that affect the intestine causing pain and swelling. URSOGRIP Tablet is not recommended for use if you have inflammatory bowel disease.

### **Warnings:**

**(i) Pregnancy:** URSOGRIP Tablet is not recommended for use during pregnancy unless absolutely necessary. All the risks and benefits should be discussed with your doctor before taking this medicine.

**(ii) Breast-feeding:** URSOGRIP Tablet is not recommended for use while breastfeeding unless absolutely necessary. All the risks and benefits should be discussed with your doctor before taking this medicine.

### **Competitor Brands : Ursogrip**

| BRAND              | COMPANY              | Sum of MAT VAL APR'22 | Sum of MAT VAL APR'23 | Sum of MAT VAL APR'23 GR% |
|--------------------|----------------------|-----------------------|-----------------------|---------------------------|
| UDILIV             | ABBOTT*              | 445.1                 | 474.5                 | 6.6                       |
| URSOCOL            | SUN*                 | 123.4                 | 138.6                 | 12.3                      |
| HEPAKIND           | MANKIND              | 21.2                  | 30.1                  | 42.1                      |
| ULYSES             | LUPIN                | 26.3                  | 30.0                  | 14.3                      |
| GOLBI              | INTAS                | 22.8                  | 28.3                  | 24.2                      |
| URSOMAX            | EMCURE*              | 20.2                  | 22.3                  | 10.5                      |
| URSOFORD           | LEEFORD HC           | 23.0                  | 21.7                  | -5.8                      |
| URSETOR            | TORRENT              | 16.3                  | 20.0                  | 22.2                      |
| ACTIBILE           | ZYDUS*               | 12.9                  | 14.1                  | 8.9                       |
| UDIWOK             | DR. REDDYS           | 8.9                   | 13.9                  | 56.3                      |
| SORBIOL            | FRANCO               | 11.4                  | 12.1                  | 6.2                       |
| URDOHEP            | MACLEODS             | 8.8                   | 11.2                  | 28.4                      |
| URSOKEM            | ALKEM*               | 10.9                  | 10.4                  | -4.2                      |
| USIBON             | MICRO                | 8.3                   | 10.2                  | 23.4                      |
| SEDOGEST           | LA RENON             | 6.6                   | 7.5                   | 14.2                      |
| URSOCAD            | CADILA               | 6.6                   | 6.7                   | 1.7                       |
| FORTIBILE          | DEYS MEDICAL         | 4.4                   | 6.5                   | 48.8                      |
| URSODOX            | SIGNOVA PHARMA       | 5.5                   | 6.4                   | 15.9                      |
| UDGRACE            | ALNICHE LIFE SCIENCE | 6.1                   | 5.5                   | -10.5                     |
| UDIMARIN           | FOURRTS              | 4.1                   | 5.4                   | 29.5                      |
| UDIHEP             | WIN-MEDICARE         | 5.7                   | 4.9                   | -14.3                     |
| UDCAMENT           | AKUMENTIS            | 3.4                   | 4.1                   | 21.2                      |
| URSODIL            | ZYDUS*               | 2.7                   | 3.3                   | 24.2                      |
| URSOBIAC           | MYLAN                | 1.8                   | 3.2                   | 81.7                      |
| LIQUIBIL           | MACKENZIE PHARMACE   | 3.2                   | 3.1                   | -4.3                      |
| SHINOLIV           | SHINE                | 2.5                   | 3.1                   | 24.7                      |
| OPEN UP (ALB)      | ALBERT DAVID         | 2.5                   | 2.9                   | 18.5                      |
| UDIRON             | KAMRON               | 2.5                   | 2.8                   | 13.5                      |
| HEPEXA             | ERISLS               | 2.0                   | 2.7                   | 36.9                      |
| URDIOGEM           | ALEMBIC              | 3.1                   | 2.7                   | -13.7                     |
| UDIMARIN FORTE     | FOURRTS              | 2.2                   | 2.6                   | 17.9                      |
| <b>Grand Total</b> |                      | <b>846.6</b>          | <b>931.6</b>          | <b>10.0</b>               |