

## Udihep<sup>®</sup> Forte (Ursodeoxycholic Acid Tablets BP, 300 mg)

### **PACKAGE LEAFLET: INFORMATION FOR THE USER**

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**Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider or pharmacist.

#### **What is in this leaflet?**

1. What Udihep Forte is and what it is used for?
2. What you need to know before you take Udihep Forte?
3. How to take Udihep Forte?
4. Possible side effects?
5. How to store?
- 6 Contents of the pack and other information

#### **1. What Udihep Forte is and what it is used for?**

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Ursodeoxycholic Acid (Ursodiol) is a naturally occurring bile acid. The various mechanisms of action of this hydrophilic bile acid include direct cytoprotection, improvement in hepatic excretory function including induction of hypercholeresis, antioxidative effect and immunomodulation

Udihep Forte is used:

1. For the treatment of patient with chronic cholestatic liver diseases in particular primary biliary cirrhosis, primary sclerosing cholangitis and cholestasis associated with cystic fibrosis.
2. For the dissolution of radiolucent, non-calcified gall bladder stones (which are less than 10 mm in diameter) in patients with functional gall bladder. It is also indicated in patients for whom elective cholecystectomy cannot be undertaken due to presence of increased surgical risk due to systemic diseases, advanced age, idiosyncratic reaction to general anaesthesia, or for those patients who refuse surgery.
3. For the prevention of gall stone formation in obese patients experiencing rapid weight loss due to intensive dieting and for patients who are prone to developing gall bladder stones.
4. For relief of symptoms of cholestasis in the management of chronic hepatitis, intrahepatic cholestasis of pregnancy and cirrhosis.
5. For relief of symptoms of cholestasis in post-liver transplant rejection, graft-versus-host disease, alcoholic and non-alcoholic steatohepatitis, and viral hepatitis.

## **2. What you need to know before you take Udihep Forte?**

### **Do not take Udihep Forte Tablets:**

If you are allergic to Ursodeoxycholic Acid or any of the other ingredient of Udihep Forte Tablets.

### **Take special care with Udihep Forte Tablets**

#### **Warnings and precautions**

This medicine must be used under medical supervision.

*Pregnancy:* Category-B. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of potential risk to the fetus.

*Lactation:* It is not known whether Ursodeoxycholic acid is excreted in human milk. Caution should be exercised when Ursodeoxycholic acid is administered to a nursing mother.

Contact your doctor or pharmacist before you start to use this medicine.

### **Taking Other medicines with Udihep Forte**

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines. This also applies for medicines obtained without a prescription.

The effect of the following drugs can be influenced (interactions):

Cholestyramine or colestipol may interfere with the action of Ursodeoxycholic acid by reducing its absorption. Aluminium based antacids have been shown to absorb bile acid *in vitro* and may be expected to interfere with Ursodeoxycholic acid in the same manner as the sequestering agents. Estrogens, oral contraceptives, and fibrates increase biliary cholesterol secretion and hence may counteract the effectiveness of ursodiol.

### **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Ursodeoxycholic Acid has no or negligible influence on driving ability or the ability to operate machines.

## **3. How to take Udihep Forte Tablets?**

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Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for cholestasis is 2-4 Tablets per day, after meals.

The recommended adult dosage for Udihep Forte in treatment of primary biliary cirrhosis is two to four Tablet per day with food.

*Gall Stone Treatment-* The recommended dose of Udihep Forte in the treatment of radiolucent gall bladder stones is 2-4 Tablets per day. Bedtime administration is advocated; the rationale is to enhance bile acid secretion during the night, when it normally is lowest and cholesterol saturation is highest.

*Gall Stone Prevention-* The recommended dose of Udihep Forte for gall stone prevention in patients undergoing rapid weight loss is 600 mg/day (300 mg twice daily).

Ursodeoxycholic Acid has been successfully used in the treatment of cholestasis of pregnancy with no ill effects to the mother or the baby. The usual starting dose is 2-4 Tablets per day.

*Treatment of Alcoholic and Non-alcoholic steatohepatitis with Ursodeoxycholic Acid 2-4 Tablets per day for 12 months resulted in significant improvement in alkaline phosphatase, ATL, GGT & hepatic steatosis.*

Ursodeoxycholic Acid has been used in the treatment of acute viral hepatitis using a daily dose of 600 mg for a period of 4 months.

### **If you take more Udihep Forte Tablets than recommended**

You should tell your doctor if you have taken more Ursodeoxycholic Acid Tablets than recommended. It is unlikely that you will notice any problems, but rarely you may experience diarrhoea.

### **If you forget to use Udihep Forte Tablets**

Take the prescribed amount at the next regular taking time.

Do not take a double dose to make up for a forgotten dose.

### **How long should you use Udihep Forte Tablets?**

The duration of the treatment depends upon the extent of disease, or the size of the gallstone but is usually not shorter than three to four months. Treatment should not be interrupted prematurely, even if the symptoms have disappeared. Only an Ultrasound image of the gallbladder should be obtained at 6-months intervals for the first year of Udihep Forte therapy to monitor gall stone response. If gallstones appear to have dissolved, Udihep Forte therapy should be continued, and dissolution confirmed on a repeat ultrasound examination within 1 to 3 months.

### **4. Possible side effects?**

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The following side effects have been reported with the use of Ursodeoxycholic acid: diarrhoea, exacerbation of pre-existing psoriasis, rash, urticaria, dry skin, sweating, hair thinning, leucopenia, stomatitis, flatulence, headache, fatigue, anxiety, depression, sleep disorder, arthralgia, myalgia, back pain, cough, and rhinitis.

### **5. How to store Udihep Forte Tablets?**

Keep this medicine out of the sight and reach of children.

Store protected from light and moisture at a temperature not exceeding 30°C.

Do not use this medicine after the expiry date which is stated on the blister strip and carton.

The expiry date refers to the last day of that month.

## **6. Other information**

### **What Udihep Forte Tablets contains?**

- The active substance is Ursodeoxycholic acid
- The other ingredients are Croscarmellose Sodium, Colloidal Anhydrous Silica, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Povidone K-30

### **What Udihep Forte Tablets looks like and contents of the pack?**

White, round, flat, uncoated tablets, with score on one facet and engraved with 'UDIHEP FORTE' on the other facet.

Udihep Forte are packed in blisters supplied in box containing 50 Tablets.

### **Marketed by:**

Win-Medicare Pvt. Ltd.  
1400, Modi Tower,  
98, Nehru Place,  
New Delhi – 110019, India.

### **Manufactured by:**

Win-Medicare Pvt. Ltd.  
Modipuram – 250 110,  
U.P., India.

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