SUMMARY OF PRODUCT CHARACTERISTICS

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1. Trade name of medicinal product
Udihep Forte

2. Qualitative and Quantitative Composition

S. No.	Name of Excipients	Concentration (mg/tablet)	Reference to Standard	Function
1.	Ursodeoxycholic Acid	300.00	BP	Gall Stone solubilizing agent
2.	Croscarmellose Sodium (Ac-Di-Sol)	10.00	BP	Disintegrant
3.	Colloidal Anhydrous Silica (Aerosil -200)	1.20	BP	Lubricant
4.	Lactose	40.80	BP	Diluent
5.	Magnesium Stearate	4.00	BP	Glidant & Lubricant
6.	Microcrystalline Cellulose (Avicel PH-102)	28.00	BP	Diluent
7.	Povidone (K-30)	16.00	BP	Binder
	Total	400		

3. Pharmaceutical form
Oral Tablets

4. Clinical Particulars

4.1 Therapeutic indications
Dissolution of radiolucent cholesterol gallstones. Chronic cholestatic liver diseases, in particular primary billiary cirrhosis, primary sclerosing cholangitis, and cholestasis associated with cystic fibrosis. Relieve symptoms of cholestasis in the management of chronic hepatitis, Intrahepatic cholestasis of pregnancy, cirrhosis, post liver transplant rejection, graft versus host disease, alcoholic and nonalcoholic steatohepatitis, and viral hepatitis.

4.2 Posology and Method of Administration
Adults and children: the recommended dose is 8 to 15 mg/kg/day which may be given in 2 to 4 divided doses, after meals.

4.3 Contraindications
Hypersensitivity to bile acids; radio-opaque stones; non-functioning gall bladder.

4.4 Special warnings and special precautions for use

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 ursodiol is excreted in human milk. Caution should be exercised when ursodiol is administered to a nursing mother.

4.5 Interaction with other medicinal products and other forms of Interaction

Cholestyramine or colestipol may interfere with the action of ursodiol by reducing its absorption. Aluminium based antacids have been shown to absorb bile acid *in vitro* and may be expected to interfere with ursodiol 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.

4.6 Pregnancy and lactation

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

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

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Side effects

The following side effects have been reported with the use of ursodeoxycholic: 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.

4.9 Overdose and its treatment

Accidental or intentional over dosage of ursodiol has not been reported and would probably result only in self-limiting acute diarrhoea, which should be treated symptomatically. Monitor liver function tests. May use ion-exchange resins.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ursodeoxycholic Acid (Ursodiol) is a naturally occurring bile acid. The various mechanisms of action of this hydrophilic bile acid include direct cytoprotection, detergent action on dysfunctional microtubules, immunomodulation and induction of hypercholeresis.

5.2 Pharmacokinetic properties

About 90% of a therapeutic dose of ursodiol is absorbed in the small bowel after oral administration. After absorption, ursodiol enters the portal vein and undergoes extraction from portal blood by the liver (i.e., "first-pass" effect) where it is conjugated with either glycine or taurine and is then secreted into the hepatic bile ducts. Ursodiol in bile is concentrated in the gall bladder and expelled into the duodenum in gallbladder bile via the cystic and common ducts by gallbladder contractions produced by physiological responses to eating.

Small quantities of ursodiol appear in the systemic circulation and very small amounts are excreted into urine. A small portion of orally administered drug undergoes bacterial degradation with each cycle of enterohepatic circulation. Ursodiol can be both oxidized and reduced, yielding either 7-keto-lithocholic acid or Lithocholic acid, respectively. Free Ursodiol, 7-keto-lithocholic acid and Lithocholic acids are relatively insoluble in aqueous media and larger proportions of these compounds are excreted via the feces. Reabsorbed free ursodiol is reconjugated by the liver. Eighty percent of the Lithocholic acid formed in the small bowel is excreted in the feces, but the 20% that is absorbed is sulfated in the liver to relatively insoluble lithocholyl conjugates which are excreted into bile and lost in feces. Absorbed 7-keto-lithocholic acid is stereo specifically reduced in the liver to chenodiol.

5.3 Preclinical safety data

Single oral doses of Ursodiol at 10, 5 and 10 g/kg in mice, rats and dogs, respectively were not lethal. A single oral dose of Ursodiol at 1.5 g/kg was lethal in hamsters. Symptoms of acute toxicity were salivation and vomiting in dogs, and ataxia, dyspnea, ptosis, agonal convulsions and coma in hamsters.

6. Pharmaceutical Particulars

6.1 List of Excipients

S. No.	Name of Excipients
1.	Croscarmellose Sodium (Ac-Di-Sol)
2.	Colloidal Anhydrous Silica (Aerosil -200)
3.	Lactose
4.	Magnesium Stearate
5.	Microcrystalline Cellulose (Avicel PH-102)
6.	Povidone (K-30)

6.2 Incompatibilities

None of the incompatibilities has been reported.

6.3 Shelf life

24 months

6.4 Special precautions for storage

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

6.5 Nature and content of container

Udihep Forte are packed in blisters of printed aluminum foil width (100mm, thickness 0.025 mm) backed with clear rigid PVC film width (104mm and thickness 0.250 mm).

Pack size

Box of 5x 10's

6.6 Instructions for use/handling

Keep the medicine out of reach of the children

The tablets should be swallowed whole and not chewed.

7. **Marketing Authorization Holder**
   Win-Medicare Pvt. Ltd.
   1311, Modi Tower
   98, Nehru Place
   New Delhi – 110019, India.

8. **Marketing Authorization Number**
   Fresh Registration

9. **Date of first Authorization/Renewal of the Authorization**
   Fresh Registration

10. **Date of Revision of the Text**
    April, 2019