PRODUCT INFORMATION

1.3 Product Information

1.3.1 Summary of Product Characteristics

Summary of product characteristic is attached.

SUMMARY OF PRODUCT CHARACTERISTICS

1. Trade Name of Medicinal Product

Udihep Forte
(Ursodeoxycholic Acid Tablets BP)

2. Qualitative and Quantitative Composition

Ingredients	Quantity mg / tablet	Active / Non-active	Reference to standard	Reason for inclusion
Ursodeoxycholic Acid	300.00	Active	BP	Gallstone solubilizing agent
Croscarmellose Sodium (Ac-Di-Sol)	10.00	Non-active	BP	Disintegrant
Colloidal Anhydrous Silica (Aerosil -200)	1.20	Non-active	BP	Lubricant
Lactose	40.80	Non-active	BP	Diluent
Magnesium Stearate	7.00	Non-active	BP	Glidant & Lubricant
Microcrystalline Cellulose (Avicel PH 102)	25.00	Non-active	BP	Diluent
Povidone (K-30)	16.00	Non-active	BP	Binder
Total	**400.00**			

3. Pharmaceutical Form

Tablets (Oral dosage form)

4. Clinical Particulars

4.1 Therapeutic Indications

Dissolution of radiolucent cholesterol gallstones. Chronic cholestatic liver diseases, in particular primary biliary 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 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.

4.7 Effects on Ability to Drive and Use Machines

Not Applicable

4.8 Undesirable 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

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 Mode of Action

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.

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 Pre Clinical 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 protected from light and moisture at a temperature not exceeding 30 °C

6.5 Nature and Content of Container

Primary Packaging

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).

Secondary Packaging

The blister strip of 5x 10s is packaged in an outer carton comprising of Laminated Indian duplex board with tucking on both sides and contain a package insert comprising of Cream wove art paper.

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.

7.0 MARKETING AUTHORISATION HOLDER

Win-Medicare Pvt. Ltd.

8.0 MARKETING AUTHORISATION NUMBER(S)

B4-1628

9.0 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th Feb 2014

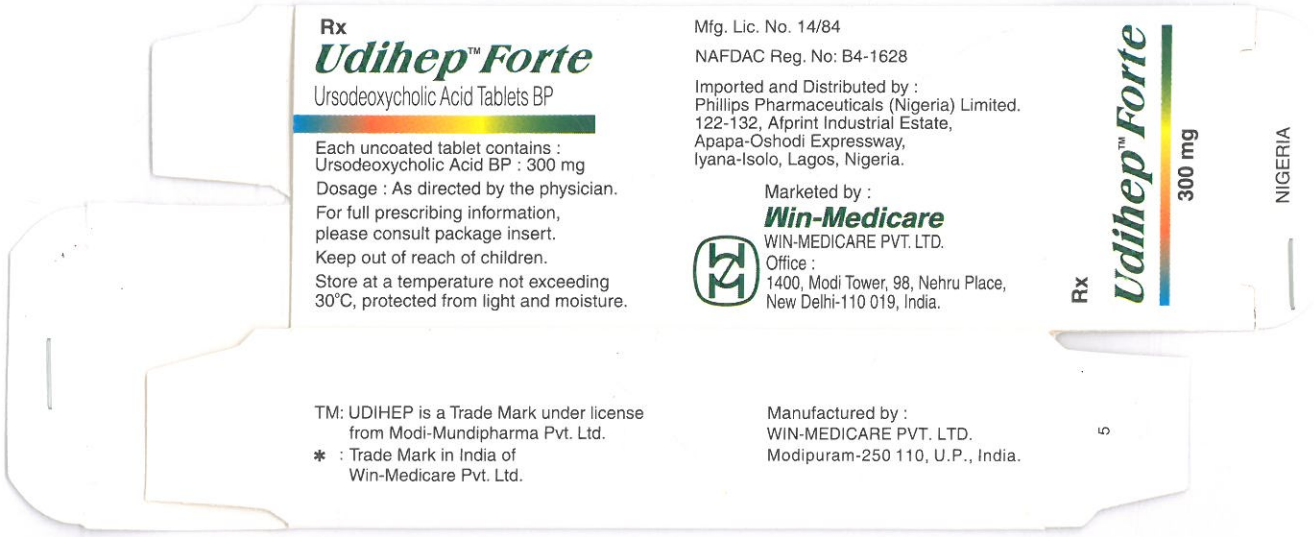
10.0 DATE OF REVISION OF THE TEXT

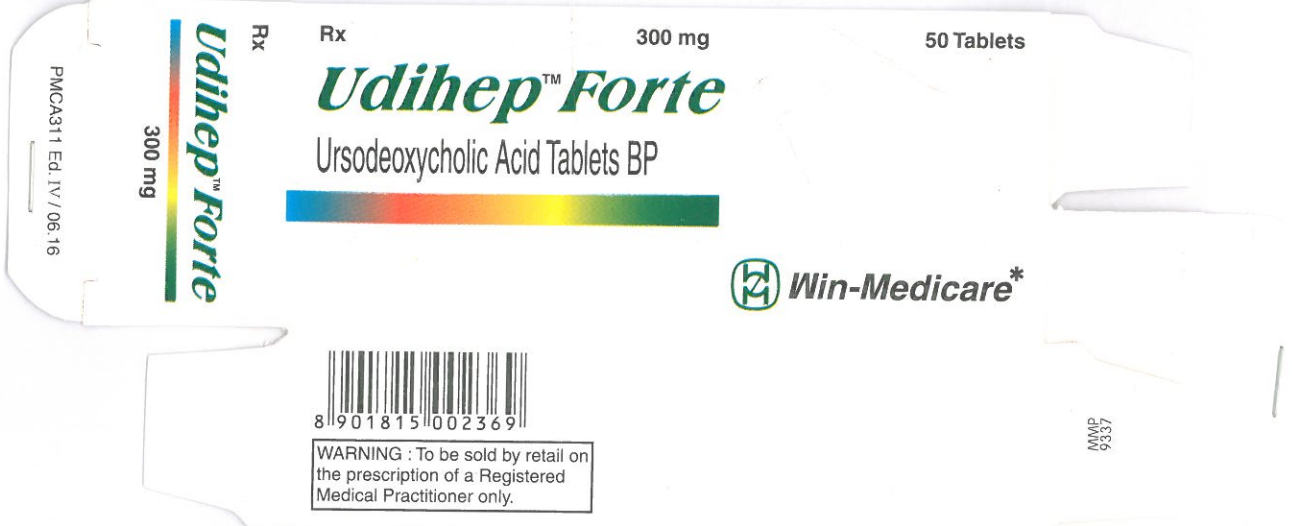
12th Dec.2019

1.3.2 Labelling (outer & inner labels)

Please find the enclosed artworks of Udihep Forte tablets.

IMMEDIATE AND OUTER LABEL


Rx
Udihep™ Forte
Ursodeoxycholic Acid Tablets BP
Each uncoated tablet contains :
Ursodeoxycholic Acid BP : 300 mg
Dosage : As directed by the physician.
For full prescribing information,
please consult package insert.
Keep out of reach of children.
Store at a temperature not exceeding
30°C, protected from light and moisture.
Mfg. Lic. No. 14/84
NAFDAC Reg. No: B4-1628
Imported and Distributed by :
Phillips Pharmaceuticals (Nigeria) Limited.
122-132, Afprint Industrial Estate,
Apapa-Oshodi Expressway,
Iyana-Isolo, Lagos, Nigeria.
Marketed by :
Win-Medicare
WIN-MEDICARE PVT. LTD.
Office :
1400, Modi Tower, 98, Nehru Place,
New Delhi-110 019, India.
Rx
Udihep™ Forte
300 mg
NIGERIA
TM: UDIHEP is a Trade Mark under license
from Modi-Mundipharma Pvt. Ltd.
* : Trade Mark in India of
Win-Medicare Pvt. Ltd.
Manufactured by :
WIN-MEDICARE PVT. LTD.
Modipuram-250 110, U.P., India.
5


Rx
Udihep™ Forte
300 mg
PMCA311 Ed. IV / 06.16
Rx
300 mg
50 Tablets
Udihep™ Forte
Ursodeoxycholic Acid Tablets BP
Win-Medicare*
8 901815 002369
WARNING : To be sold by retail on
the prescription of a Registered
Medical Practitioner only.
MMP
9337

Rx Udihep™ Forte 300mg
Ursodeoxycholic Acid Tablets BP
Dosage : As directed by the physician.
Manufactured by : WIN-MEDICARE PVT. LTD., Modipuram-250 110, U.P., India.
TM: UDIHEP is a Trade Mark under license from Modi-Mundipharma Pvt. Ltd.
NAFDAC Reg. No: B4-1628
Imported and Distributed by :
Phillips Pharmaceuticals (Nigeria) Limited.
122-132, Afprint Industrial Estate,
Apapa-Oshodi Expressway,
Iyana-Isolo, Lagos, Nigeria.
Keep out of reach of children.
Mfg. Lic. No. 14/84
PMAL239 Ed. III / 04.14 NIGERIA

1.3.3 Packaging Insert (also known as patient information PIL)

Pack insert of Udihep Forte tablets is enclosed.

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Rx

Udihep™ Forte

Ursodeoxycholic Acid Tablets BP

Composition :

Each uncoated tablet contains :
Ursodeoxycholic Acid BP : 300 mg

Actions :

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.

Indications:

Dissolution of radiolucent cholesterol gallstones. Chronic cholestatic liver diseases, in particular primary biliary 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 non-alcoholic steatohepatitis, and viral hepatitis.

Dosage :

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.

Contraindications :

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

Precautions :

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.

Drug interactions : 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 billary cholesterol secretion and hence may counteract the effectiveness of ursodiol.

Side Effecs :

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

Overdosage :

Accidental or intentional overdosage 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.

Storage :

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

Keep out of reach of children.

Shelf life :

24 months from date of manufacturing.

Presentation :

Box of 50 tablets (5 strips of 10 tablets each).

Manufactured by :
WIN-MEDICARE PVT. LTD.
Modipuram-250 110, U.P., India.

NAFDAC Reg. No: B4-1628

Imported and Distributed by :
Phillips Pharmaceuticals (Nigeria) Limited.
122-132, Afprint Industrial Estate,
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Iyana-Isolo, Lagos, Nigeria.

Marketed by:
Win-Medicare
WIN-MEDICARE PVT. LTD.
Office :
1400, Modi Tower, 98, Nehru Place,
New Delhi-110 019, India.

NIGERIA

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