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

Rx

Udihep®

Ursodeoxycholic Acid Tablets BP

Composition :
Each uncoated tablet contains :
Ursodeoxycholic Acid BP : 150 mg

Description:
White, round, flat, uncoated tablets, with score on one facet and embossed with 'UDIHEP' on the other facet.

Indications :
1. For the treatment of patients 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.

Actions :
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.

Pharmacokinetics :
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 via the cystic and common ducts as a result of gall bladder 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 both be oxidized and reduced, yielding either 7-keto-lithocholic acid or lithocholic acid, respectively. Free ursodiol, 7-keto-lithocholic acid and lithocholic acid 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 lithocholic acid formed in the small bowel is excreted in the feces, but the 20% that is absorbed is sulphated in the liver to relatively insoluble lithocholyl conjugates which are excreted into the bile and lost in the feces. Absorbed 7-keto-lithocholic acid is stereospecifically reduced in the liver to chenodiol.

Dosage and Administration:

The recommended dose for cholestasis is 8-15 mg/ kg/ day, in 2-4 divided doses, after meals.

The recommended adult dosage for Udihep® in the treatment of Primary biliary cirrhosis is 13-15 mg/kg/day administered in two to four divided doses with food.

Gall Stone Treatment-The recommended dose of Udihep® treatment of radiolucent gall bladder stones is 8-15 mg/kg of body weight/day given in 2 - 4 divided doses. 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.

Ultrasound images of the gall bladder should be obtained at 6-months intervals for the first year of Udihep® therapy to monitor gall stone response. If gallstones appear to have dissolved, Udihep® therapy should be continued and dissolution confirmed on a repeat ultrasound examination within 1 to 3 months. Most patients who eventually achieve complete stone dissolution will show partial or complete dissolution at the first on-treatment re-evaluation. If partial stone dissolution is not seen by 12 months of Udihep® therapy, the likelihood of success is greatly reduced.

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

Ursodiol 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 8-15 mg/kg/day.

Treatment of Alcoholic and Non-alcoholic steatohepatitis with ursodiol 8-15 mg/kg/day for 12 months resulted in significant improvement in alkaline phosphatase, ATL, GGT & hepatic steatosis.

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

Tablets must be swallowed as whole.

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 biliary cholesterol secretion and hence may counteract the effectiveness of ursodiol.

Side effects :
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 disorder, 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 protected from light & moisture at a temperature not exceeding 30°C.
Keep out of reach of children.

Shelf life :
24 months from date of manufacturing.

Presentation :
Box of 30 tablets (3 strips of 10 tablets each).

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