Ursobil®

"150 mg hard capsules" 20 capsules
"250 mg hard capsules" 20 capsules
"150 mg hard capsules" 40 capsules
"250 mg hard capsules" 30 capsules

URSODEOXYCHOLIC ACID

PHARMACOTHERAPEUTIC GROUP
Biliary and liver treatment
THERAPEUTIC INDICATIONS
Ursodeoxycholic acid has a cholesterol-solubilizing capacity in the bile. Treatment with ursodeoxycholic acid causes desaturation of cholesterol saturated bile.
Qualitative or quantitative alterations of the biligenetic function, including forms of oversaturated bile in cholesterol for preventing the formation of the cholesterol calculi or for realising the suitable conditions in order to have the dissolution of radiotransparent calculi if they are already present: in particular calculi of cholecystic type in working cholecystis and calculi remaining in the choledocus or occurring after operations on the biliary tracts. Biliary dyspepsias.
CONTRAINDICATIONS
Hypersensitivity to the active substance, to biliary acids or to any of the excipients.
Ursobil should not be administered to patients affected by:
a) Acute inflammation of the gallbladder or biliary tract.
b) Occlusion of the biliary tract (occlusion of the common bile duct or a cystic duct).
c) Frequent episodes of biliary colic.
d) Radio-opaque calcified gallstones.
e) Impaired contractility of the gallbladder.
PRECAUTIONS FOR USE
Patients with frequent episodes of biliary colic, biliary infection, severe pancreatic alterations or intestinal conditions interfering with enterohepatic circulation of bile acids (ileal resection and stoma, regional ileitis, etc...) should not take this medicine. In case of long-term treatment for dissolution it is necessary to check levels of transaminases and alkaline phosphatase before beginning therapy.
INTERACTIONS
Please tell your doctor or pharmacist if you have recently taken any other medicines, including medicines obtained without a prescription. Ursodeoxycholic acid should not be administered concomitantly with colestyramine, colestipol or antacids containing aluminium hydroxide and/or smectite (aluminium oxide), because these preparations bind ursodeoxycholic acid in the intestine and thereby inhibit its absorption and efficacy. Should the use of a preparation containing one of these substances be necessary, it must be taken at least 2 hours before or after ursodeoxycholic acid. Ursodeoxycholic acid can increase the absorption of ciclosporin from the intestine. In patients receiving ciclosporin treatment, blood concentrations of this substance should therefore be checked by the physician and the ciclosporin dose adjusted if necessary. In isolated cases ursodeoxycholic acid can reduce the absorption of ciprofloxacin. Ursodeoxycholic acid has been shown to reduce the plasma peak concentrations (Cmax) and the area under the curve (AUC) of the calcium antagonist nitrendipine. An interaction with a reduction of the therapeutic effect of dapsone was also reported. These observations together with in vitro findings indicate a potential for ursodeoxycholic acid to induce cytochrome P450 3A enzymes. Oestrogenic hormones and blood cholesterol lowering agents such as clofibrate may increase biliary lithiasis, which is a counter-effect to ursodeoxycholic acid used for dissolution of gallstones. Combination with drugs increasing the biliary elimination of cholesterol (estrogen, hormonal contraceptives, some lipid-lowering medicines) should be avoided.
SPECIAL WARNINGS
Ursodeoxycholic acid should be taken under medical supervision. During the first 3 months of treatment, the liver function parameters AST (SGOT), ALT (SGPT) and γ-GT should be monitored by the physician every 4 weeks, thereafter every 3 months. Apart from allowing for identification of responders and non-responders patients being treated for primary biliary cirrhosis, this monitoring would also enable early detection of potential hepatic deterioration, particularly in patients with advanced stage primary biliary cirrhosis. When used for the dissolution of cholesterol gallstones:
In order to assess therapeutic progress and for timely detection of any calcification of the gallstones, depending on stone size, the gall bladder should be visualised (oral cholecystography) with overview and occlusion views in standing and supine positions (ultrasound control) 6-10 months after the beginning of treatment. If the gall bladder cannot be visualised on X-ray images, or in cases of calcified gallstones, impaired contractility of the gall bladder or frequent episodes of biliary colic, ursodeoxycholic acid should not be used. When used for treatment of advanced stage of primary biliary cirrhosis: In very rare cases decompensation of hepatic cirrhosis has been observed, which partially regressed after the treatment was discontinued. If diarrhoea occurs, the dose must be reduced and in cases of persistent diarrhoea, the therapy should be discontinued.
PREGNANCY AND LACTATION
Ask your doctor or pharmacist for advice before taking any medicine.
There are no adequate data on the use of ursodeoxycholic acid, particularly in the first trimester of pregnancy. Animal studies have provided evidence of a reproductive toxicity during the early phase of gestation. Ursodeoxycholic acid must not be used during pregnancy unless clearly necessary. Women of childbearing potential should be treated only if they are using reliable contraception: non-hormonal or low-oestrogen oral contraceptive measures are recommended. However, in patients taking ursodeoxycholic acid for dissolution of gallstones, effective non-hormonal contraception should be used, since hormonal oral contraceptives may increase biliary lithiasis. The possibility of a pregnancy must be excluded before beginning treatment. It is not

known whether ursodeoxycholic acid passes into breast milk. Therefore, ursodeoxycholic acid should not be taken during lactation. If treatment with ursodeoxycholic acid is necessary, breastfeeding must be discontinued.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No effects on ability to drive and use machines have been observed.

IMPORTANT INFORMATION ABOUT SOME INGREDIENTS

Ursobil 150 mg hard capsules contains lactose. If you have been told by your doctor that you have intolerance to some sugar, contact your doctor before taking this medicinal product.

POSOLOGY AND METHOD OF ADMINISTRATION

Long-term therapy: to reduce lithogenic characteristics of bile, the average daily dose is 5-10 mg/kg in 2-3 divided doses. To maintain the right conditions for the dissolution of the existing gallstones, the duration of treatment should be at least 4-6 months, up to 12 months. In dyspeptic syndromes and maintenance therapy doses of 330 mg per day, in 2-3 divided doses are sufficient. The doctor may decide to adjust the dose; in particular the excellent tolerability of this medicine allows to administer even much higher doses. Ursodeoxycholic acid is to be taken preferably during and after meal.

OVERDOSE

If you take accidentally more Ursobil than you should, consult your doctor or the nearest hospital straight away.

If you have further questions on the use of Ursobil ask your doctor or pharmacist.

Diarrhoea may occur in cases of overdose. In general, other symptoms of overdose are unlikely because the absorption of ursodeoxycholic acid decreases with increasing dose and therefore more is excreted with the faeces. No specific counter-measures are necessary and the consequences of diarrhoea should be treated symptomatically with restoration of fluid and electrolyte balance. In case of accidental ingestion of high doses of ursodeoxycholic acid, it is suggested to implement the measures recommended for normal conditions of intoxication and to administer cholestyramine, as capable of chelate bile acids.

UNDESIRABLE EFFECTS

Like all medicines, Ursobil can cause side effects, although not everybody gets them.

The evaluation of undesirable effects is based on the following frequency data:

Very common (≥ 1/10),

Common (≥ 1/100 to < 1/10),

Uncommon (≥ 1/1000 to < 1/100),

Rare (≥ 1/10000 to < 1/1000)

Very rare (< 1/10000),

Not known (cannot be estimated from the available data).

Gastrointestinal disorders:

In clinical trials, reports of pasty stools or diarrhoea during ursodeoxycholic acid therapy were common.

Very rarely, severe right upper abdominal pain has occurred during the treatment of primary biliary cirrhosis.

Hepatobiliary disorders:

During treatment with ursodeoxycholic acid, calcification of gallstones can occur in very rare cases. During therapy of the advanced stages of primary biliary cirrhosis, in very rare cases decompensation of hepatic cirrhosis has been observed, which partially regressed after the treatment was discontinued.

Skin and subcutaneous disorders:

Very rarely, urticaria can occur.

The product at the recommended dose is usually well tolerated. Irregularities in bowel habits were reported only occasionally, they usually disappear during the treatment. Observance of directions contained in the package leaflet reduces the risk of side effects. If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

SHELF LIFE AND STORAGE

Shelf-life: see the expiry date shown on the package. The expiry date refers to the product which has been properly stored in its undamaged, unopened package.

Caution: do not use the medicinal product after the expiry date shown on the package.

Medicines should not be disposed or via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Keep out of the reach and sight of children.

COMPOSITION

Each capsule contains:

Active ingredient:

Ursodeoxycholic acid: 150 mg 250 mg

List of excipients:

Lactose, magnesium stearate, colloidal silica, polyvinylpyrrolidone, gelatin, titanium dioxide (E171), iron oxide yellow (E172).

NATURE AND CONTENTS OF CONTAINER

150 mg capsules, pack containing 20 and 40 capsules

250 mg capsules, pack containing 20 and 30 capsules

MARKETING AUTHORIZATION HOLDER

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MANUFACTURER

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