URSETOR

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

Abbreviated Prescribing information for URSETOR [Ursodeoxycholic Acid Tablets I.P. (Ursodiol Tablets)]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Ursodeoxycholic acid, a naturally occurring bile acid found in small quantities in normal human bile and in the bile of certain other mammals. It suppresses hepatic synthesis and secretion of cholesterol, and also inhibits intestinal absorption of cholesterol.

INDICATIONS: It is indicated for the treatment of patients with chronic cholestatic liver disease.

DOSAGE AND ADMINISTRATION: The dosage should be calculated based on the patient's body weight. The calculated dosage should be rounded to the nearest number of tablets. Usual dosage: 8 to 10 mg/kg/day, corresponding to, for example, four to six 150 mg tablets, or two to three tablets of 300 mg, or two tablets of 450 mg. The daily dose can be administered two or three times after the meals: two tablets should always be taken after the evening meal. The dosage of ursodeoxycholic acid in primary biliary cholangitis (stages I-III), amounts to 12-15 mg/kg/day, which is equivalent to four to eight tablets of 150 mg, two to four tablets of 300 mg, to be taken in two to three portions during the day, or with two tablets of 450 mg, to be taken in two portions during the day. If the patient has difficulty in swallowing because of the size of the tablet, the tablet can be halved if necessary on the dividing score, so that one half tablet can be taken twice directly in sequence.

CONTRAINDICATION: Ursodeoxycholic acid tablets should not be used in patients with: •Acute inflammation of the gall bladder or bile ducts. •Occlusion of the biliary tract (occlusion of the common bile duct or a cystic duct). •Frequent episodes of biliary colic. •X-ray radiolucent calcified gallstones. •Impaired contractility of the gallbladder. •Hypersensitivity to bile acids or to any of the excipients. •Active gastric and duodenal ulcers. •Unsuccessful portoenterostomy or without recovery of good bile flow in children with biliary atresia.

WARNINGS & PRECAUTIONS: During the first three months of the treatment liver function parameters AST (SGOT), ALT (SGPT) and γ-GT should be monitored by the physician every 4 weeks, thereafter every 3 months. If the gallbladder cannot be visualized on X-rays, or in cases of calcified gallstones, impaired contractility of the gall bladder or frequent episodes of biliary colic, the treatment with Ursodeoxycholic acid should be discontinued. In very rare cases decompensation of liver cirrhosis is observed which partially decreased after treatment discontinuation. In patients with PBC, the clinical symptoms may worsen in rare cases at the start of treatment, e.g. pruritus may increase. In this case, the therapy is to be continued with a dose reduction and subsequently should be gradually increased to the recommended dose. If diarrhoea occurs, the dosage should be reduced, and treatment should be discontinued in case of persistent diarrhoea. Female patients who use Ursodeoxycholic acid for dissolving gall stones must use an effective non-hormonal method of contraception, since hormonal contraception may increase biliary lithiasis.

DRUG INTERACTIONS: Ursodeoxycholic acid tablets should not be used concurrently with colestyramine, colestipol, or an antacid, on the basis of aluminium hydroxide and/or smectite (aluminium oxide), because these preparations bind ursodeoxycholic acid in the intestine and thereby inhibits its absorption and efficacy. In patients treated with ciclosporin the blood level of ciclosporin should be monitored and the ciclosporin dose should be adjusted, if necessary. Close monitoring of the outcome of concurrent use of nitrendipine and ursodeoxycholic acid is recommended. Oestrogens and blood cholesterol lowering agents such as clofibrate increase hepatic cholesterol secretion and may therefore encourage biliary lithiasis; which is a counter-effect to ursodeoxycholic acid used for

dissolution of gallstones.

ADVERSE REACTIONS: *Gastrointestinal disorders*: In clinical studies, reports of pasty stools or diarrhoea during treatment with ursodeoxycholic acid were common. In very rare cases, severe right upper abdominal pain has occurred during the treatment of primary biliary cholangitis. *Hepatobiliary disorders*: During treatment with ursodeoxycholic acid calcification of gallstones can occur in very rare cases. During the treatment of advanced stages of primary biliary cholangitis decompensation of cirrhosis has been observed in very rare cases, which partially regressed after treatment discontinuation. *Hypersensitivity reactions*: Very rarely urticaria may occur.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/URSETOR 150 mg and 300 mg/MAR-2026/02/ABPI

(Additional information is available on request)