URSETOR SR

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

Abbreviated Prescribing information for URSETOR SR (Ursodeoxycholic acid sustained releasetablets 450mg) [Please refer the complete prescribing information available atwww.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: 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.

INDICATION: For the dissolution of radiolucent cholesterol gallstone, chronic cholestatic liver diseases in paricular primary biliary cirrhosis, primary sclerosing cholangitis and cholestasis associated with cyatic fibrosis.

DOSAGE AND ADMINISTRATION: The daily dose depends on body weight and ranges from 1½ to 3½ tablets (14 ± 2 mg of UDCA per kg of body weight). For the first 3 months of treatment, Ursetor SR tablets should be taken divided over the day.With improvement of the liver values the daily dose may be taken once daily in the evening. Approximately 10mg of UDCA per kg of body weight for dissolution of cholesterol gallstones.

CONTRAINDICATION: Not for patients with acute inflammation of the gall bladder or biliary tract, occlusion of the biliary tract, frequent episodes of biliary colic, radio-opaque calcified gallstones, impaired contractility of the gall bladder and hypersensitivity to bile acids or any excipient of the formulation.

WARNINGS & PRECAUTIONS: During the first 3 months of treatment, 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 in patients being treated for PBC, this monitoring would also enable early detection of potential hepatic deterioration, particularly in patients with advanced stage PBC. 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 visualized. 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, Ursetor SR should not be used.

DRUG INTERACTIONS: Interactions with bile acid sequestering agents such as cholestyramine and colestipol, albumin–based antacids, estrogens, oral contraceptives, and clofibrate (and perhaps other lipid lowering drugs) when administered concomitantly.

ADVERSE REACTIONS: urticaria, pasty stools or diarrhoea. During therapy of the advanced stages of PBC, in very rare cases decompensation of hepatic cirrhosis has been observed, which partially regressed after the treatment was discontinued.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/ URSETOR SR 450mg/APR 2016/01/AbPI

(Additional information is available on request)