

URSETOR SR

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

Abbreviated Prescribing information for URSETOR SR [Ursodeoxycholic Acid Sustained Release Tablet 450 mg]

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

DOSAGE AND ADMINISTRATION: As directed by the Physician.

CONTRAINDICATION: • 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 excipient.

WARNINGS & PRECAUTIONS: 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. 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: 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: Pasty stools, diarrhoea, right upper abdominal pain, calcification of gallstones, cirrhosis, urticaria.

MARKETED BY:

TORRENT
PHARMA

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(Additional information is available on request)