Surliv™

Ursodeoxycholic Acid BP Film Coated Tablet

DESCRIPTION

Surliv™ is a preparation of Ursodeoxycholic Acid (Ursodiol). Ursodiol, a naturally occurring hydrophilic bile acid, derived from cholesterol, is present as a minor fraction of the total human bile acid pool. Oral administration of ursodiol increases this fraction in a dose related manner, to become the major biliary acid, replacing toxic concentrations of endogenous hydrophobic bile acids that tend to accumulate in cholestatic liver disease. In addition to the replacement and displacement of toxic bile acids, other mechanisms of action include cytoprotection of the injured bile duct epithelial cells (cholangiocytes) against toxic effects of bile acids, inhibition of apotosis of hepatocytes, immunomodulatory effects, and stimulation of bile secretion by hepatocytes and cholangiocytes.

INDICATION

Ursodeoxycholic Acid is indicated in the treatment of primary biliary cirrhosis (PBC) and for the dissolution of radiolucent (non radio opaque) cholesterol gallstone in patients with a functioning gallbladder, non alcoholic fatty liver disease (NAFLD) and viral hepatitis.

DOSAGE AND ADMINISTRATION

The tablet should be taken for various disease purposes according to the following table:

Indication	Dosage
Primary biliary cirrhosis	13-15 mg/kg/day in four divided doses.
Dissolution of cholesterol rich gallstone	8-12 mg/kg/day either as single night time dose or in divided doses
NAFLD	13-15 mg/kg/day
Acute viral hepatits	600 mg/day

USE IN SPECIFIC POPULATION

Pregnancy

Pregnancy Category B. There are no adequate or well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether Ursodeoxycholic Acid is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ursodeoxycholic Acid is administered to a nursing mother.

Pediatric Use

The safety and effectiveness of Ursodeoxycholic Acid in pediatric patients have not been established.

DRUG INTERACTIONS

Bile acid sequestering agents such as cholestyramine and colestipol may interfere with the action of Ursodeoxycholic Acid by reducing its absorption. Aluminum based antacids have been shown to adsorb bile acids in vitro and may be expected to interfere with Ursodeoxycholic Acid in the same manner as the bile acid sequestering agents. Estrogens, oral contraceptives and clofibrate (and perhaps other lipid-lowering drugs) increase hepatic cholesterol secretion and encourage cholesterol gall stone formation and this may reduce the effect of Ursodeoxycholic Acid.

CONTRAINDICATIONS

Known hypersensitivity or intolerance to Ursodeoxycholic Acid or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Patients with variceal bleeding, hepatic encephalopathy, ascites or in need of an urgent liver transplant, should receive appropriate specific treatment.

SIDE EFFECTS

Calcification of gallstones, nausea, vomiting, pruritus, diarrhoea and elevated plasma transaminase activity may occur during treatment.

OVERDOSE

There have been no reports of accidental or intentional overdose with Ursodeoxycholic Acid. Single oral doses of Ursodeoxycholic Acid at 10 g/kg in mice and dogs, and 5 g/kg in rats were not lethal. A single oral dose of Ursodeoxycholic Acid at 1.5 g/kg was lethal in hamsters. Symptoms of acute toxicity were salivation and vomiting in dogs, and ataxia, dyspnea, ptosis, agonal convulsions and coma in hamsters.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Surliv™ 150 FCT: Box containing 2 strips of 10 tablets each. Each film coated tablet contains Ursodeoxycholic Acid BP 150 mg.

Surliv™ 300 FCT: Box containing 2 strips of 10 tablets each. Each film coated tablet contains Ursodeoxycholic Acid BP 300 mg.

***To be dispensed only by the prescription of a registered physician.**

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

PM08887 V01