

Liveric®

Ursodeoxycholic Acid

Tablet

Description

Ursodeoxycholic Acid is a biliary composition and flow-altering drug occurring naturally in mammals. Ursodeoxycholic Acid reduces cholesterol content of biliary fluid and also to reduces the absorption of cholesterol from the gut.

Indication and Usage

Liveric® tablets are indicated for the dissolution of small to medium sized radiolucent, cholesterol-rich gall stones in patients with a functioning gall bladder and primary biliary cirrhosis (in which the bile ducts are damaged, causing bile to accumulate in the liver, which is then damaged itself).

Cholesterol stones coated with calcium or stones composed of bile pigments are not dissolved by Ursodeoxycholic Acid. Liveric® has a particular place in the treatment of patients in whom surgery is contraindicated or who are anxious to avoid surgery.

Dosage and Administration

Liveric® tablets should be taken orally just after taking food with a glass of water. For dissolution of gallstones, usual adult dose is 8–12 mg/kg daily as a single dose or in two divided doses for up to 2 years; treatment is continued for 3–4 months after stones dissolve. For Primary biliary cirrhosis, usual adult dose is 12–16 mg/kg daily in 3 divided doses for 3 months, then 12–16 mg/kg once daily.

Contraindications

Ursodeoxycholic Acid is contra-indicated in pregnant and lactating women, in patients

with acute inflammation of the gall bladder or obstruction of the common bile duct (biliary obstruction), chronic liver disease (except primary biliary cirrhosis), peptic ulcers or inflammatory bowel disease such as ulcerative colitis or Crohn's disease, and in treating gallstones containing high calcium content (opaque on an X-ray).

Precautions

In primary biliary cirrhosis, liver function should be monitored every 4 weeks for the first 3 months, then every 3 months. Treatment with this medicine for gallstones may have to be continued for up to two years, depending on the size of the gallstones. Regular check-ups should be done to see if the medicine is helping to dissolve the gallstones. Treatment with this medicine should be continued for three to four months after the gallstones have dissolved.

Side Effects

Diarrhoea during Ursodeoxycholic Acid therapy is common. Very rarely abdominal pain, gallstone calcification, urticaria are observed. Nausea, vomiting, pruritus were also reported.

Overdose

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 feces.

No specific counter-measures are necessary and the consequences of diarrhoea should be treated symptomatically with restoration of

fluid and electrolyte balance.

Use in Pregnancy and Lactation

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 teratogenic effect during the early phase of gestation. That is why, Ursodeoxycholic Acid should not be used during pregnancy. It is not known whether Ursodeoxycholic Acid passes into breast milk. Therefore, Ursodeoxycholic Acid should not be taken during lactation.

Drug Interaction

Antacids, charcoal, colestyramine, or colestipol bind with Ursodeoxycholic Acid in the intestine and thereby inhibit its absorption and efficacy. Hence, these preparations should not be taken at the same time as or within two hours of taking Ursodeoxycholic Acid. Ursodeoxycholic Acid can increase the absorption of cyclosporin from the intestine. In isolated cases Ursodeoxycholic Acid can reduce the absorption of ciprofloxacin. Oral contraceptives, estrogenic 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.

Pharmaceutical Precautions

Keep in a cool & dry place. Protect from light. Keep out of the reach of children.

Commercial Pack

Liveric® 150 tablet: Box containing 30 tablets in 3x10's blister strips. Each film coated tablet contains Ursodeoxycholic Acid BP 150 mg.

Liveric® 300 tablet: Box containing 30 tablets in 3x10's blister strips. Each film coated tablet contains Ursodeoxycholic Acid BP 300 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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