Antigal

Ursodeoxycholic Acid Tablet

Presentation

Antigall [™] 150 Tablet: Each film-coated tablet contains Ursodeoxycholic Acid BP 150 mg. Antigall™ 300 Tablet: Each film-coated tablet contains Ursodeoxycholic Acid BP 300 mg.

Description

Ursodeoxycholic Acid is a naturally occurring bile acid used to treat different hepatobilliary disorders. It decreases the secretion of cholesterol in different ways in the bile: Ursodeoxycholic Acid reduces cholesterol absorption and suppresses liver cholesterol synthesis. But it does not inhibit bile acid synthesis.

Indications

- Dissolution of small to medium sized radiolucent, noncalcified gall bladder stones in functioning gall bladders
- Prevention of gallstone formation in obese patients experiencing rapid weight loss
- · Primary biliary cirrhosis

Dosage & administration

For adults & elderly:

- Dissolution of gallstone: 8 10 mg/kg/day given in 2 or 3 divided doses.
- Prevention of gallstone formation: 300 mg twice daily.
- Primary biliary cirrhosis: 13 15 mg/kg/day in 2 to 4 divided doses with food.

Contraindications

This medicine is contraindicated in calcified cholesterol stones, radio-opaque stones, radiolucent bile pigmented stones; and in patients with acute cholecystitis, biliary obstruction, gallstone pancreatitis, biliary-gastrointestinal fistula and who are allergic to bile acids.

Side effects

This drug may give rise to nausea, vomiting, dizziness, headache, dyspepsia, diarrhea, abdominal pain and pruritus.

Excessive diatery intake of calories and cholesterol should be avoided. Liver function tests and bilirubin levels should be monitored every month for three months after start of therapy, and every six months thereafter.

Use during pregnancy and lactation

Pregnancy category B. There is no adequate and well-controlled studies in pregnant and lactating women. This drug should be used only if the benefit outweighs the risk. It is not known whether Ursodeoxycholic Acid is excreted in human milk. So, caution should be exercised when it is administered to a lactating mother.

Drug interactions

This drug should not be administered with oral contraceptive, oestrogenic hormones and other drugs which reduce the blood cholesterol level and increase the bile cholesterol level. Concomitant administration with bile acid binding drugs including antacids, charcoal and cholestyramine should be avoided. Since this may reduce the effectiveness of the therapy with Ursodeoxycholic Acid.

Overdosage

It is unlikely that overdose will cause serious side effects. Diarrhoea may occur and it is recommended that liver function test to be monitored

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

Commercial Pack

Antigall[™] 150 tablet: Each box contains 3 Alu-PVDC blister strips of 10 tablets.

Antigall ** 300 tablet: Each box contains 2 Alu-PVDC blister strips of 10 tablets.



Manufactured by

→ Incepta Pharmaceuticals Ltd

Savar, Dhaka, Bangladesh

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