

## AGALSTONE TABLET

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Generic name: Ursodeoxycholic Acid

Category: Anticholelithic

Composition: Each 150mg tablet contains Ursodeoxycholic acid 150mg

Each 300mg tablet contains Ursodeoxycholic acid 300mg

Presentation: 10 Tablets X 10 Blisters

### MOLECULAR INTRODUCTION

Ursodeoxycholic acid (UDCA), is a compound produced from bile by the action of intestinal bacteria. Since this bile acid is not produced directly by the body, it is known as a secondary bile acid. One of the functions of bile acids is to act in the intestine to help digest fats and fat-soluble vitamins from food. Ursodeoxycholic acid has been used in pharmacology to dissolve gallstones made of cholesterol, and to treat liver disorders. It has been used for a long time in both human and veterinary medicine.

### MECHANISM OF ACTION

Ursodeoxycholic acid reduces elevated liver enzyme levels by facilitating bile flow through the liver and protecting liver cells. The main mechanism is anticholelithic. Although the exact process of ursodeoxycholic acid's anticholelithic action is not completely understood, it is thought that the drug is concentrated in bile and decreases biliary cholesterol by suppressing hepatic synthesis and secretion of cholesterol and by inhibiting its intestinal absorption. The reduced cholesterol saturation permits the gradual solubilization of cholesterol from gallstones, resulting in their eventual dissolution.

### INDICATIONS

- Primary biliary sclerosis
- Sclerosing Cholangitis
- Alcoholic Cirrhosis,
- Biliary Cirrhosis,
- Hepatic disease
- Gallstone disease (treatment)
- Gallstone formation (prophylaxis)

### PHARMACOKINETICS

Ursodeoxycholic acid suppresses hepatic synthesis and secretion of cholesterol and also inhibits intestinal absorption of cholesterol.

**Absorption:** Rapidly and completely absorbed from the GI tract.

**Distribution:** Protein binding: 96-98%. Undergoes enterohepatic recycling.

**Metabolism:** Partly conjugated in the liver before being excreted into the bile. Free and

conjugated forms undergo 7 $\alpha$ -dehydroxylation to lithocholic acid under the influence of gut bacteria. Some are reabsorbed and then further conjugated and sulfated by the liver.

**Excretion:** Faeces.

## **DOSAGE REGIMEN**

To be taken with a drink of water.

### **Primary Biliary Cirrhosis**

Adults and Elderly: 10 - 15mg ursodeoxycholic acid (UDCA) per kg per day in two to four divided doses.

Children: Dosage should be related to bodyweight.

### **Dissolution of gallstones**

Adults and Elderly:

The usual dose is 6 - 12mg/kg/day either as a single night time dose or in divided doses. This may be increased to 15mg/kg/day in obese patients, if necessary.

The duration of treatment may be up to two years, depending on the size of the stone(s), and should be continued for three months after the apparent dissolution of the stone(s).

Children: Dosage should be related to bodyweight.

### **Hepatic disease, Cholestatic (treatment):**

Oral, 13 to 15 mg per kg of body weight a day, given in two divided doses (morning and bedtime) with food.

## **SIDE/ADVERSE EFFECTS**

Back pain, diarrhea—may be dose-related, Incidence less frequent or rare, Alopecia (hair loss), constipation, dizziness, dyspepsia (heartburn), nausea, psoriasis.

For further information, please contact:

**Market Planning Department**



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