

# **Ursodeoxycholic acid**

## **UDCACID 300**

300 mg Tablet

*Bile Salt*

### **FORMULATION:**

Each tablet contains:

Ursodeoxycholic acid.....300 mg

### **DESCRIPTION:**

White, round tablet, scored on one side marked with "D/W" on the top and "300" on the bottom.

### **INDICATIONS:**

It is used for the dissolution of cholesterol-rich gallstones in patients with functioning gallbladders. It is also used in primary biliary cirrhosis.

### **PHARMACOKINETICS:**

Ursodeoxycholic acid is absorbed from the gastrointestinal tract and undergoes enterohepatic recycling. It is partly conjugated in the liver before being excreted into the bile. Under the influence of intestinal bacteria, the free and conjugated forms undergo 7 $\alpha$ -dehydroxylation to lithocholic acid, some of which is excreted directly in the feces and the rest is absorbed and mainly conjugated and sulfated by the liver before excretion. However, in comparison with chenodeoxycholic acid, less ursodeoxycholic acid undergoes such bacterial degradation.

### **DOSAGE & ADMINISTRATION:**

Adult: 300 mg, three times a day, with meals.

Or as prescribed by the physician.

### **PRECAUTIONS:**

Ursodeoxycholic acid should not be given to patients with peptic ulcer disease, inflammatory bowel disease, or chronic liver disease. Its use should be avoided in pregnancy.

### **CONTRAINDICATIONS:**

Do not administer the drug to the following patients:

Patients with hypersensitivity to its components.

Patients with complete obstruction of biliary tract (choleretic actions may aggravate the symptoms).

Patients with fulminant hepatitis.

Patients with radiopaque calcifying cholelithiasis.  
Patients with nonfunctioning gall bladder or acute cholecystitis.  
Pregnant women or women suspected of being pregnant.  
Pediatric patients.  
Patients with renal disease.  
Patients with gastric ulcers (acute gastroduodenal ulcers).  
Patients with colitis or enteritis such as Crohn's disease.

The drug should be administered with caution in the following patients:  
Careful administration should be exercised in patients with jaundice and hepatic cirrhosis. Regularly check the level of liver enzymes (e.g., ALT, AST,  $\gamma$ -GT, ALP, total bilirubin).

There is a faint chance that an overdose causes a severe adverse event. If necessary, perform a liver function test.

There is no evidence that dose adjustment in geriatric patients is necessary. However, appropriate precautions should be exercised such as reducing the dose because the physical functions of elderly patients generally decline.

#### **ADVERSE REACTIONS:**

Diarrhea, vomiting, nausea, abdominal pain, constipation, heartburn, and epigastric discomfort.

Hypersensitivity: itchiness, rashes.

Interstitial pneumonia: fever, cough, dyspnea.

Rarely, general malaise, dizziness, calcification of cholelithiasis, increase in ALT, ALP, AST,  $\gamma$ -GT, decrease in leukocyte.

Increase in serum bilirubin.

#### **GENERAL PRECAUTIONS:**

The following patients should see a physician before taking this drug.

Patients with severe pancreatic disease.

Patients with choledocholithiasis.

Patients with variceal bleeding, hepatic encephalopathy, ascites and those in need of an urgent liver transplantation.

#### **DRUG INTERACTIONS:**

Concurrent administration of oral hypoglycemic agent (Tolbutamide); should be cautiously administered to patients with diabetes because ursodeoxycholic acid may increase the effects of oral hypoglycemic agents.

The following may reduce the absorption of this drug:

Cholestyramine, cholestipol, charcoal, aluminum hydroxide and magnesium-based antacids.

Cholesterol-reducing drugs in bile (e.g., Oral contraceptives containing estrogens) or cholesterol-reducing drugs in serum (e.g., clofibrate).

Drugs which induce liver injury.

#### **CAUTION:**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**AVAILABILITY:**

Alu-PVC Blister Pack x 10's (box of 30's)

**STORE AT TEMPERATURES NOT EXCEEDING 30°C.**

For suspected adverse drug reaction, report to the FDA: [www.fda.gov.ph](http://www.fda.gov.ph)  
Seek advice from a healthcare professional at the first sign of any adverse drug reaction.

**DRP-3895-01**

***Pharma  
Nutria***

Distributed by

**PHARMA NUTRIA N.A., INC.**

2nd Floor, S.V. More Group Corporate Center  
# 16 Scout Tuazon cor. Roces Ave., Quezon City  
Metro Manila, Philippines

Manufactured by:

**DAEWOONG**

PHARMACEUTICAL CO., LTD.

35-14, Jeyakgongdan 4-gil, Hyangnam-eup,  
Hwaseong-si, Gyeonggi-do, Korea

Imported by:

**DAEWOONG**

PHARMA PHILIPPINES INC.

Unit 1701, 17th Floor, One World Place Condominium,  
32nd Street, Bonifacio Global City  
Fort Bonifacio, Taguig, Metro Manila