

URUSA- ursodeoxycholic acid capsule
OASIS TRADING

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Ursodeoxycholic Acid

Improve liver function of chronic liver disease

Improvement of the following symptoms due to hepatic dysfunction: physical fatigue, general boredom

Keep out of reach of children

1 capsule once, three times a day

Do not take this medicine if

■ Patients with hypersensitivity to this component ■ Patients with severe biliary obstruction ■ Fulminant hepatitis (may aggravate symptoms) ■ Radiopaque calcified gallstone Patient ■ Non-functional gallbladder patient, acute cholecystitis ■ Pregnant or pregnant women and lactating woman ■ Pediatric ■ Renal disease patient ■ Patient with peptic ulcer (acute gastroduodenal ulcer)

■ Patients with colon and small intestine such as Crohn's disease .

Do not take the following medicines while taking this medicine.

■ there is a risk of increasing the action of the following drugs: Oral diabetes (tolbutamide) ■ The following medications interfere with the absorption of this drug : cholestyramine, cholestipol, Antacids containing ■ Avoid using drugs that reduce cholesterol in the bile (eg estrogen-containing oral contraceptives) or drugs that reduce blood cholesterol

Consult a doctor, dentist or pharmacist before taking this medicine

■ Patients with severe pancreatic disease (may cause worsening of the original disease) ■ Patients with gallstones in the bile ducts (can cause cholestasis due to dysfunction) ■ Varicose bleeding, hepatic coma, ascites, Patients with diabetes

Stop taking this drug immediately and consult a doctor, dentist, or pharmacist if you have any of the following conditions: Whenever possible, bring this attached document with you.

■ Digestive system: Sometimes diarrhea, nausea, vomiting, infrequent abdominal pain, constipation, heartburn, and stomach discomfort may occur. ■ Hypersensitivity: Occasionally itching, rare rashes may occur ■ Interstitial pneumonia: If you develop fever, cough, dyspnea, or interstitial pneumonia accompanied by abnormal chest X-ray, discontinue use and consult your doctor, dentist or pharmacist.

thiamine nitrate, Riboflavin, gelatin, soybean oil

For oral use only

URUSA

Drug Facts

Active Ingredients (in one capsule)
Ursodeoxycholic Acid 250 mg

Purpose

Liver function improvement

Uses

Improve liver function of chronic liver disease
Improvement of the following symptoms due to hepatic dysfunction: physical fatigue, general boredom

Warnings

Do not take this medicine if

- Patients with hypersensitivity to this component
- Patients with severe biliary obstruction
- Fulminant hepatitis (may aggravate symptoms)
- Radiopaque, calcified gallstone Patient
- Non-functional gallbladder patient, acute cholecystitis
- Pregnant or pregnant women and lactating woman
- Pediatric
- Renal disease patient
- Patient with peptic ulcer (acute gastroduodenal ulcer)
- Patients with colon and small intestine such as Crohn's disease

Do not take the following medicines while taking this medicine.

- there is a risk of increasing the action of the following drugs:
Oral diabetes (tolbutamide)
- The following medications interfere with the absorption of this drug : cholestyramine, colestipol.
- Antacids containing
- Avoid using drugs that reduce cholesterol in the bile (eg, estrogen-containing oral contraceptives) or drugs that reduce blood cholesterol

Consult a doctor, dentist or pharmacist before taking this medicine

- Patients with severe pancreatic disease (may cause worsening of the original disease)
- Patients with gallstones in the bile ducts (can cause cholestasis due to dysfunction)
- Varicose bleeding, hepatic coma, ascites, Patients with diabetes

Stop taking this drug immediately and consult a doctor, dentist, or pharmacist if you have any of the following conditions:

Whenever possible, bring this attached document with you.

- Digestive system: Sometimes diarrhea, nausea, vomiting, infrequent abdominal pain, constipation, heartburn, and stomach discomfort may occur.
- Hypersensitivity: Occasionally itching, rare rashes may occur
- Interstitial pneumonia: If you develop fever, cough, dyspnea, or interstitial pneumonia accompanied by abnormal chest X-ray, discontinue use and consult your doctor, dentist or pharmacist.

Keep out of reach of children

Directions

- 1 capsule once, three times a day

Other Information

- Store at room temperature

Inactive Ingredient

thiamine nitrate, Riboflavin, gelatin, soybean oil

Questions or comments ?

Call weekdays from 9 a.m to 5 p.m. EST at (201) 669-8405

Distributed By: P&K FRONTIER MARKETING CORP.

329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA

Made in South Korea

URUSA

ursodeoxycholic acid capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72689-0001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
URSODIOL (UNII: 724L30 Y2QR) (URSODIOL - UNII:724L30 Y2QR)	URSODIOL	250 mg

Inactive Ingredients

Ingredient Name	Strength
RIBOFLAVIN (UNII: TLM2976 OFR)	
GELATIN (UNII: 2G86QN327L)	
SOYBEAN OIL (UNII: 241ATL177A)	
THIAMINE MONONITRATE (UNII: 8K0I04919 X)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	URSA
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72689-0001-1	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/15/2018	

Labeler - OASIS TRADING (689991468)

Registrant - OASIS TRADING (689991468)

Establishment

Name	Address	ID/FEI	Business Operations
OASIS TRADING		689991468	manufacture(72689-0001)

Revised: 11/2018

OASIS TRADING