

# URSOSAN, 250 mg hard capsules

Ursodeoxycholic Acid (250 mg)

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## What Ursosan is used for

Ursosan is indicated for:

- dissolution of cholesterol gallstones in the gallbladder. The gallstones must not show as shadows on X-ray images and should not exceed 15 mm in diameter. The gallbladder function must not be significantly impaired, despite the gallstones.
- treatment of bile reflux gastritis.
- symptomatic treatment of primary biliary cirrhosis (PBC), in patients without decompensated hepatic cirrhosis.

## How Ursosan works

Ursodeoxycholic acid (UDCA) is found in small amounts in human bile.

Upon oral administration, it induces a decline in cholesterol saturation of the gallbladder through blocking of cholesterol resorption in the intestine and decline in cholesterol secretion to the gall. A gradual decomposition of cholesterol gallstones is presumably achieved through dispersion of cholesterol and forming of liquid crystals.

## Before you use Ursosan

### - When you must not use it

Do not take Ursosan if

- you are, or have been told you are, allergic (hypersensitive) to bile acids like UDCA or to any of the other ingredients of this product.

- you have an acute inflammation of the gallbladder or biliary tract.
- you have a blockage of the common bile duct or cystic duct (obstruction of the biliary tract).
- you have frequent cramp-like pains in the upper abdomen (biliary colic).
- your doctor has said you have calcified gallstones (they are visible on an x-ray).
- your gallbladder does not work properly.

Please ask your doctor about any of the conditions mentioned above. You should also ask if you have previously had any of these conditions or if you are unsure whether you have any of them.

### - Before you start to use it

#### **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ursosan must not be used during pregnancy unless clearly necessary. Women of childbearing potential should be treated only if they use reliable contraception: non-hormonal or low-oestrogen oral contraceptive measures are recommended. However, in patients taking Ursosan for dissolution of gallstones, effective non-hormonal contraception should be used, since hormonal oral contraceptives may stimulate the formation of gallstones. The possibility of a pregnancy must be excluded before beginning treatment.

### - Taking other medicines

The effects of these medicines may be altered:

A **reduction in the effects** of Ursosan is possible when taking it with the following medicines:

- cholestyramine, colestipol (used to lower blood lipid levels) or

antacids containing aluminium hydroxide or smectite (aluminium oxide) (used to bind stomach acid): If you must take medication that contains any of these substances, it must be taken at least two hours before or after Ursosan.

A **reduction in the effects** of the following medicines is possible when taking Ursosan:

- ciprofloxacin and dapsone (antibiotics), nitrendipine (used to treat high blood pressure). It may be necessary for your doctor to alter the dose of these medicines.

A **change in the effects** of the following medicines is possible when taking Ursosan:

- ciclosporin (to reduce the activity of the immune system). If you are being treated with ciclosporin, your doctor should check the amount of ciclosporin in your blood. Your doctor will adjust its dose, if necessary.
- rosuvastatin (for high cholesterol and related conditions).

If you are taking Ursosan for the dissolution of gallstones, please inform your doctor, in case you are taking any medicines that contain oestrogenic hormones or blood cholesterol lowering agents such as clofibrate. These medicines stimulate the formation of gallstones, which is a counter-effect to the treatment with Ursosan.

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, even if they are medicines obtainable without a prescription. Treatment with Ursosan may still be allowed. Your doctor will know what is right for you.

## How to use Ursosan

### - How much to use

For dissolution of cholesterol gallstones, the recommended dose

in adult patients is dependent on the body weight (10 mg/kg/day).

For the treatment of bile reflux gastritis, the recommended dose is 1 capsule once daily in the evening before bedtime.

For the symptomatic treatment of primary biliary cirrhosis (PBC), the daily dose depends on the body weight and usually is 12-16 mg/kg/day.

Ursosan needs to be taken regularly.

Talk to your doctor or pharmacist before taking Ursosan. Your doctor will know what is right for you.

**- How long to use it**

It generally takes 6-24 months to dissolve gallstones. If there is no reduction in the size of the gallstones after 12 months, therapy should be stopped.

Every 6 months, your doctor should check whether the treatment is working.

For the treatment of bile reflux gastritis Ursosan should normally be taken for 10-14 days. The treating physician will decide on the duration of use in the individual case.

For the treatment of PBC, use of Ursosan may be continued indefinitely.

**- If you forget to use it**

If you forget to take Ursosan, continue at your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

**- If you use too much (overdose)**

Diarrhoea may occur in overdose with UDCA. In this case, the dose must be reduced, and if diarrhoea persists, the treatment must be discontinued. Please inform your doctor immediately if you have persistent diarrhoea. If you do suffer from diarrhoea, make sure you drink enough liquids to replace your fluid and electrolyte balance.

**While you are using it**

**- Things you must do**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**- Things you must not do**

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

**- Things to be careful of**

Talk to your doctor or pharmacist before taking Ursosan.

Your doctor should test your liver function regularly every 4 weeks for the first 3 months of treatment. After this time, it should be monitored at 3 months intervals.

When used in the treatment of PBC, in rare cases the symptoms may worsen at the beginning of treatment. If this happens, please speak to your doctor about reducing your initial dose.

When used to dissolve gallstones, your doctor should arrange for a scan of your gall bladder after the first 6-10 months of treatment.

Please inform your doctor immediately if you have diarrhoea, as this may require a reduction in the dose or discontinuation of treatment.

**Side effects**

Like all medicines, Ursosan can cause side effects, although not everybody gets them.

**Common side effects:**

- soft, loose stools or diarrhoea.

**Very rare side effects:**

- during the treatment of PBC: severe right-sided upper abdominal pain, severe worsening of liver scarring - this partially eases after treatment is stopped.
- hardening of gallstones due to build-up of calcium. There are no additional symptoms of this but it will show up in tests.
- nettle rash (urticaria).

**Effects on ability to drive and use machines**

Ursodeoxycholic acid has no or negligible influence on the ability to drive and use machines.

**Storage and Disposal of Ursosan**

**- Storage**

Store at temperatures not exceeding 30 °C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "Expiry date". The expiry date refers to the last day of that month.

**- Disposal**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**Product Description**

**- What it looks like**

Hard capsule.

White, hard gelatin capsules containing white or almost white powder.

**- Ingredients**

- Active Ingredient:  
Ursodeoxycholic Acid.
- Inactive Ingredient:  
Maize starch, pregelatinised starch, silica colloidal anhydrous, magnesium stearate, titanium dioxide and gelatin.

**Manufacturer**

PRO.MED.CS Praha a.s.  
Telčská 377/1  
Michle, 140 00 Praha 4  
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**Product Registration Holder**

PharmEng Technology Pte. Ltd.  
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**Date of revision**

29/11/2023

**Serial Number**