

PACKAGE LEAFLET: INFORMATION FOR THE USER

URSOSAN

250mg capsule, hard

URSODEOXYCHOLIC ACID

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What URSOSAN is and what it is used for
2. Before you take URSOSAN
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1. WHAT URSOSAN IS AND WHAT IS IT USED FOR

URSOSAN contains ursodeoxycholic acid. Ursodeoxycholic acid is a bile acid, which is produced naturally in human bile.

URSOSAN may be used

- For dissolution of gallstones formed from cholesterol. Gallstones should not be seen in X-radiation and should not be greater than 15 mm in diameter. Gallbladder should be functional regardless of the presence of gallstones.
- For the treatment of inflammation of the stomach wall caused by bile acid reflux (bile reflux gastritis).
- For the treatment of primary biliary cirrhosis (PBC) (chronic disease of the bile duct that leads to progressive cholestasis and often end-stage liver disease).

2. BEFORE YOU TAKE URSOSAN

Do not take URSOSAN

- if you are hypersensitive to Ursodeoxycholic acid or to any of the other ingredients of the medicine
- if you have acute inflammation of the gallbladder or biliary tract

- if you have biliary tract occlusion (closing the main bile duct or cystic duct)
- if you suffer from frequent pain like cramps in the upper abdomen (biliary colic)
- if you have calcified gallstones (which can be seen on X-ray)
- if you suffer from severe kidney or liver disorder
- if your gallbladder is not working (not shrinking) properly

Please ask your doctor about any of the above conditions. You need to ask your doctor if you had any of these conditions.

Warnings and Precautions

URSOSAN should be used only under medical supervision.

In the first three months of treatment, your doctor should monitor liver function every 4 weeks. After this time, liver function should be monitored every 3 months.

If you are taking this medicine to dissolve gallstones, your doctor should evaluate the effect of treatment after 6-10 months by X-ray examination.

If you are a woman and you are taking URSOSAN to dissolve gallstones, you should use non-hormonal contraception, because the application of hormonal contraceptives may enhance the formation of gallstones. If you are taking this medicine for the treatment of primary biliary cirrhosis (PBC), in rare cases, the clinical symptoms (eg, itching) at the beginning of treatment may worsen. If this occurs, talk to your doctor in order to reduce the initial dose.

Please tell your doctor if you have diarrhea, as this may require dose reduction or discontinuation of treatment.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

There is a possibility for the reduction of the effects of the following medicines when taken simultaneously with the URSOSAN:

- cholestyramine or colestipol, medicines used to lower high levels of cholesterol in the blood
- ciprofloxacin, an antibiotic used to treat certain infections, nitrendipine (used to treat high blood pressure), dapsone (an anti-infective) and other medicines which are metabolised in a similar way

Increased effect of the following medicines is possible when taken simultaneously with the URSOSAN:

- cyclosporine, a medicine used to suppress the immune system
- rosuvastatin (used to treat high cholesterol levels)

If you are taking this medicine to dissolve gallstones, please notify your doctor if you are taking medicines to lower cholesterol in the blood (such as clofibrate) or medicines that contain estrogen. These medicines can enhance the formation of gallstones and neutralize the effect of ursodeoxycholic acid in the dissolution of stones.

Pregnancy and breastfeeding

Talk to your doctor before taking this or any other medicine if you are pregnant.

Fertility

Animal studies showed no effect of this medicine on fertility. There is no data available to show the impact of this medicine on fertility in humans.

Pregnancy

No data available, or there is not enough data, on the use of ursodeoxycholic acid in pregnant women. Animal studies have shown that ursodeoxycholic acid can affect the growth and development of the child. You should not take URSOSAN during pregnancy, unless your doctor considers it necessary.

Women of reproductive age

Even if you are not pregnant, you should talk to your doctor. Women of reproductive age can be treated only if they use reliable contraceptive measures. Non- hormonal contraceptives or oral contraceptives with low-dose of estrogen are recommended. If you are taking URSOSAN to dissolve gallstones, you should use non-hormonal contraception, because the application of hormonal contraceptives may enhance the formation of gallstones. Before starting treatment, your doctor should make sure you are not pregnant.

Breast-feeding

There are only a few documented cases of the use of this medicine during breast-feeding. The level of ursodeoxycholic acid in breast milk is very low and probably will not cause adverse reactions in infants.

Use in children

There is no age limit for the use of URSOSAN. The use of URSOSAN depends on the body weight and medical condition.

Driving and using machines

Medicine does not affect or its effect is insignificant on the ability to drive and use machines.

3. HOW TO TAKE URSOSAN

Always take URSOSAN exactly according to the instructions in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

Dosage:

Approximately 10 mg of ursodeoxycholic acid per kg of body weight, corresponding to:

Up to 60 kg	2 capsules
61-80 kg	3 capsules
81 -100 kg	4 capsules
over 100 kg	5 capsules

Swallow URSOSAN whole with a full glass of water, before bedtime.

Duration of treatment:

The time required for the dissolution of gallstones is usually 6-24 months. If after 12 months of treatment there is no reduction of the size of gallstones, treatment should not be continued. Every 6 months, your doctor should check whether the treatment is working. It is necessary to check whether the calcification of stones occurred in the meantime. If this is the case, the treatment should be discontinued.

Treatment of bile reflux gastritis

Dosage and administration:

Take 1 capsule daily, in the evening before bedtime, and swallow it whole with a little liquid.

Duration of treatment:

The duration of treatment depends on the course of the disease and it usually lasts 10 to 14 days. The duration of treatment is determined by your doctor depending on the course of the disease.

Treatment of primary biliary cirrhosis (chronic inflammatory disease of the bile duct)

Dosage:

In the first three months of therapy URSOSAN capsules should be taken in divided doses in the morning, noon and evening. After the improvement of liver values daily dose may be taken once daily in the evening.

Body weight (kg)	Number of capsules			
	first 3 months			then
	morning	noon	evening	evening (1 x daily)

47 – 62	1	1	1	3
63 – 78	1	1	2	4
79 – 93	1	2	2	5
94 – 109	2	2	2	6
over 110	2	2	3	7

Duration of treatment:

The use of URSOSAN for the treatment of primary biliary cirrhosis is not time limited.

Note

If you are suffering from primary biliary cirrhosis, at the beginning of treatment the symptoms may worsen (eg. Itching). It happens in rare cases. If this occurs, treatment should be continued with a reduced daily dose of medicine. Each week your doctor will increase the daily dose until you reach the required dose.

If you take more URSOSAN than you should

Symptoms of an overdose may include diarrhea. If you suffer from diarrhea, make sure you drink enough liquids to replace the fluid and electrolyte balance. In the case of permanent diarrhea, please immediately inform your doctor.

If you forget to take URSOSAN

If you forget to take a dose, take it as soon as you remember. Do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

Common side effects (affects less than 1 in 10 patients):

- soft stool or diarrhea.

Very rare side effects (affects less than 1 in 10,000 patients):

- during the treatment of primary biliary cirrhosis: severe pain on the right side of the upper abdomen, worsening (decompensation) of liver cirrhosis, which partially withdraws after discontinuation of therapy.
- calcification of gallstones
- hives (urticaria)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of suspected side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE URSOSAN

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after “EXP”.

Store below 25 °C.

Shelf life: 4 years.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What URSOSAN contains

The active ingredient is ursodeoxycholic acid. Each capsule contains 250 mg of ursodeoxycholic acid. The other ingredients are maize starch, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate, gelatin, titanium dioxide, purified water.

What URSOSAN looks like and contents of the pack

White, hard, gelatin capsules containing white granules.
Pack size: 50 capsules

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

PRO.MED.CS Praha a.s., Telčsko 1, 140 00 Prague 4, Czech Republic

Manufacturer of the medicinal product:

PRO.MED.CS Praha a.s., Telčsko 1, 140 00 Prague 4, Czech Republic