

URSOSAN[®] 250 MG HARD CAPSULES

Ursodeoxycholic Acid (250 mg)

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What Ursosan[®] is used for

Ursosan[®] is indicated for:

- dissolution of symptomatic, radiolucent (transparent to X-rays) cholesterol gallstones in the gallbladder less than 15 mm in diameter. The gallstones must be radiolucent, and the gallbladder function must be intact; dissolution of gallstones with or without preceding extracorporeal shock wave lithotripsy;
- cholestatic liver disease (e.g. compensated primary biliary cirrhosis, cholestasis of pregnancy).

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 gall bladder 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.

- your gall bladder does not work properly.
- your doctor has said you have calcified gallstones (they are visible on an x-ray).
- you have an acute inflammation of the gall bladder 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).

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.

- 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 dapson (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 dependent on the body weight (10 mg/kg/day).

For Cholestatic liver disease, the daily dose depends on the body

weight and usually is 10-15 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.

- When to use it

Ursosan® may be taken after meals.

- 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.

- 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).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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 below 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 "EXP". 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, Maize starch, pregelatinised, Silica colloidal anhydrous, Magnesium stearate, Titanium dioxide and Gelatin.

- MAL number

MAL20116011ARZ

Manufacturer

PRO.MED.CS Praha a.s.
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Product Registration Holder

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Distribution in Malaysia

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