

URSOFALK[®] CAPSULES

Ursodeoxycholic acid (250 mg)

What is in this leaflet

1. What Ursofalk is used for
2. How Ursofalk works
3. Before you use Ursofalk
4. How to use Ursofalk
5. While you are using it
6. Side effects
7. Storage and Disposal of Ursofalk
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

What Ursofalk is used for

- To help dissolve certain gallstones in the gallbladder without surgery.
- To treat liver diseases caused by poor bile flow, such as primary biliary cholangitis (PBC) and bile flow problems during pregnancy.

How Ursofalk works

Ursofalk contains ursodeoxycholic acid, the active substance, which is a naturally occurring bile acid. It works by changing the content of bile made by your liver. It helps to reduce cholesterol in bile, helping cholesterol gallstones to shrink and dissolve gradually over time.

Before you use Ursofalk

- When you must not use it

Do not take this medicine if:

- you are allergic to ursodeoxycholic acid or any other ingredients of this medicine (listed in Product Description).
- you have an acute inflammation of the gall bladder or biliary tract.
- you have an obstruction of the biliary tract (blockage of the common bile duct or cystic duct).
- you suffer from frequent cramp-like pains in the upper abdomen (biliary colic).
- your doctor has told you that you have calcified gallstones or you have hard gallstones that cannot be dissolved with medicine.
- your gall bladder cannot work.

- Before you start to use it

Check with your doctor or pharmacist before taking Ursofalk if:

- you have liver problems or your liver disease is severe.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Do not take this medicine if you are pregnant, unless your doctor clearly advises you to do so.

Women who can become pregnant should use reliable contraception while taking this medicine. If this medicine is used to treat gallstones, a non-hormonal contraceptive method (such as condoms or a copper intrauterine device) should be used, as hormonal contraceptives may worsen gallstones. Your doctor may also check that you are not pregnant before starting treatment.

This medicine passes into breast milk in very small amounts. It is not expected to harm a breastfed baby, but you should still check with your doctor before taking it while breastfeeding.

- Taking other medicines

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

Inform your doctor or pharmacist if you are taking:

- colestyramine, colestipol, rosuvastatin, clofibrate (cholesterol and lipid medications)
- aluminium hydroxide, smectite (antacid medications)
- ciprofloxacin, dapsone (antibiotic and anti-infective medications)
- medications containing estrogenic hormones (hormone replacement or contraceptive medications)
- nitrendipine (blood pressure medication)
- ciclosporin (immunosuppressant medication)

How to use Ursofalk

Always take this medicine exactly as prescribed by your doctor. The dose depends on your body weight and the condition being treated. Swallow the capsules whole with water. Do not open or chew the capsules.

For gallstones:

- The usual dose is 2 to 5 capsules once daily, taken in the evening at bedtime, depending on your body weight.
- Treatment usually lasts 6 months to 2 years. Your doctor will arrange regular scans to check if the gallstones are getting smaller.

For liver disease (such as primary biliary cholangitis):

- The usual dose is 3 to 7 capsules daily, depending on body weight.
- During the first few months, the dose may be taken in 2 or 3 divided doses during the day.
- Once your condition improves, your doctor may advise taking all capsules once daily in the evening.
- Treatment is usually long-term, as advised by your doctor.

Take this medicine regularly to get the best effect. If you develop persistent diarrhoea, inform your doctor, as the dose may need to be reduced or stopped.

- When to use it

Take as directed by your doctor or pharmacist.

- How long to use it

Take this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your

nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of this medicine may cause diarrhoea.

Please inform your doctor immediately if you have persistent diarrhoea. If you do suffer from diarrhoea, make sure you drink enough liquids to restore your fluid and electrolyte balance.

While you are using Ursofalk

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while using this medication.

Take Ursofalk only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Ursofalk to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

• Tell your doctor immediately if you are suffering from diarrhoea, as you may need the dose to be reduced or to stop taking Ursofalk.

• When used in the treatment of primary biliary cholangitis, in rare cases the symptoms (e.g. itching) may worsen at the beginning of treatment. If this happens, please speak to your doctor about reducing your initial dose.

• You may need regular blood tests to check your liver function, especially during the first few months of treatment.

• If this medicine is used to treat gallstones, you may need regular scans or X-rays to check whether the gallstones are shrinking.

Driving and using machines

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

Side effects

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

Possible side effects are:

Common:

- Soft, loose stools or diarrhoea

Very rare:

- severe pain in the upper right side of the stomach, especially in patients treated for liver disease
- worsening of liver condition in patients with advanced liver disease
- hardening of gallstones
- hives (urticaria)

Frequency not known:

- itching
- nausea, vomiting

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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)].

Storage and Disposal of Ursofalk

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the blister and carton.

- Disposal

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.

Product Description

- What it looks like

Ursofalk capsules are white and opaque. They contain a white powder or granules.

- Ingredients

- Active ingredient

- ursodeoxycholic acid

- Inactive ingredients

- gelatin
- colloidal silica anhydrous
- magnesium stearate
- maize starch
- sodium dodecyl sulfate
- titanium dioxide
- purified water

Source of gelatin in the capsule: bovine

Source of ursodeoxycholic acid: bovine

- MAL number:

MAL19990011ACRZ

Manufacturer

Losan Pharma GmbH

Otto-Hahn-Straße 13

79395 Neuenburg, Germany

for

DR. FALK PHARMA GmbH

Leinenweberstr. 5

79108 Freiburg im Breisgau

Germany

Product Registration Holder

DCH Auriga (Malaysia)

Sdn Bhd (719-V)

Lot 6, Persiaran Perusahaan,

Seksyen 23, 40300 Shah Alam,

Selangor.

Date of revision

30/01/2026

Serial Number

NPRA(R4/1)160126/00002