**PACKAGE LEAFLET: Information for the user**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:


# Ursofalk® capsules

The active substance is ursodeoxycholic acid.

One Ursofalk® capsule contains 250 mg ursodeoxycholic acid.

The other ingredients are:
Gelatin, colloidal silicon dioxide, magnesium stearate, maize starch, sodium dodecyl sulphate, titanium dioxide (E 171), water.

Ursofalk® capsules are available in blister packs of 50 and 100 capsules.

## 1. What Ursofalk® capsules are and what they are used for

Ursodeoxycholic acid, the active substance in Ursofalk® capsules, is a bile acid that occurs naturally in human bile, but only in small amounts.

Ursofalk® capsules are manufactured and marketed by:


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Ursofalk® capsules are used for the treatment of:
- dissolution of radiolucent cholesterol gallstones, not larger than 15 mm in diameter, and the gall bladder must still be functioning despite the gallstone(s)
- bile reflux gastritis (inflammation of the stomach lining caused by the reflux of bile acids)
- primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis

## 2. Before you use Ursofalk® capsules

**Do not use Ursofalk® capsules in case of:**
- acute inflammation of the gall bladder or biliary tract
- occlusion of the biliary tract (occlusion of the common bile duct or cystic duct)

**Take special care with Ursofalk® capsules:**
- if you have a gall bladder that cannot be visualised radiologically
- if you have calcified gallstones
- if your contractility of the gall bladder is impaired
- if you suffer from frequent biliary colic

Please also consult your doctor if these statements were applicable to you at any time in the past.

**Use in children:**
There are no age restrictions on the use of Ursofalk® capsules. The use of Ursofalk® capsules depends on body weight and the condition.

**Further precautions:**
Ursofalk® capsules must be used under medical supervision.

In the first 3 months of treatment, parameters of liver function (AST (SGOT), ALT (SGPT) and γ-GT) should be monitored by the physician every 4 weeks, thereafter every 3 months.

In order to assess the progress of treatment and detect any calcification of the gallstones in good time, depending on stone size, the gall bladder should be visualised (oral cholecystography) with overview and occlusion views in standing and supine positions (ultrasound control) 6-10 months after the beginning of treatment.

**Pregnancy:**
Studies in animals have provided evidence of teratogenic effects during the early phase of gestation.
There is insufficient experience in humans in the first three months of pregnancy. Women of child-bearing age should be treated only if they use reliable contraception. Pregnancy must be excluded before the beginning of treatment. For safety reasons, treatment should not be carried out during the first three months of pregnancy.

Since there are insufficient data on the passage of ursodeoxycholic acid into breast-milk, it must not be used during breast-feeding.

**Effects on ability to drive and use machines:**
No special precautions are necessary.

**Taking other medicines:**
Ursofalk® capsules should not be administered at the same time as colestyramine, colestipol or antacids (agents that bind gastric acid) containing aluminium hydroxide and/or smectite (aluminium oxide), because these preparations bind ursodeoxycholic acid in the intestine and thus reduce its absorption and effectiveness. Should the use of a preparation containing one of these substances be necessary, it must be taken at least 2 hours before or after Ursofalk® capsules.

Ursofalk® capsules can increase the absorption of ciclosporin (an agent that reduces the activity of the immune system) from the intestine. In patients receiving treatment with ciclosporin, the physician should therefore check ciclosporin concentrations in the blood, and adjust the ciclosporin dose if necessary.

In isolated cases, Ursofalk® capsules can reduce the absorption of ciprofloxacin.

Ursodeoxycholic acid reduces the availability of nitrendipine in the blood. On the basis of this, together with a single case report of an interaction with the substance dapsone (reduction of the therapeutic effect) and certain in-vitro assays, it may be assumed that ursodeoxycholic acid increases the activity of certain enzymes that break down drugs.
Caution should therefore be exercised in co-administration of drugs that are metabolised via this enzyme, and a dose adjustment may be necessary.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

## 3. How to take Ursofalk® capsules

Always take Ursofalk® capsules exactly as instructed by your doctor. You should check with your doctor or pharmacist if you are unsure.

For the dissolution of cholesterol gallstones

Approx. 10 mg per kg body weight (BW) daily, equivalent to:
2 capsules for patients up to 60 kg BW
3 capsules for patients weighing 61–80 kg BW
4 capsules for patients weighing 81–100 kg BW
5 capsules for patients over 100 kg BW

The capsules should be swallowed whole with some liquid in the evening at bedtime. The capsules must be taken regularly.

The time required for dissolution of gallstones is generally 6-24 months. If there is no reduction in the size of the gallstones after 12 months, the therapy should not be continued.

The success of treatment should be checked by ultrasound investigation or cholecystography every 6 months. At the follow-up examinations, a check should be made to see whether calcification of the stones has occurred in the meantime. Should this be the case, the treatment must be stopped.

For the treatment of bile reflux gastritis

Swallow whole one Ursofalk® capsule daily with some liquid in the evening at bedtime.

For the treatment of bile reflux gastritis, Ursofalk® capsules should generally be taken for 10–14 days. In general, the duration of use depends on the course of the condition. The doctor responsible for treatment decides on the duration of use on an individual basis.

For the symptomatic treatment of primary biliary cirrhosis

The daily dose depends on body weight, and is approx. 2 to 6 capsules (approx. 10 to 15 mg ursodeoxycholic acid per kg body weight). The following scheme for taking the medicine is recommended:

| Body weight | Daily dose | morning | midday | evening |
|---|---|---|---|---|
| 34 to 50 kg | 2 capsules | 1 | – | 1 |
| 51 to 65 kg | 3 capsules | 1 | 1 | 1 |
| 66 to 85 kg | 4 capsules | 1 | 1 | 2 |
| 86 to 110 kg | 5 capsules | 1 | 2 | 2 |
| over 110 kg | 6 capsules | 2 | 2 | 2 |

The capsules should be swallowed whole with some liquid. Care should be taken to ensure that they are taken regularly.

The use of Ursofalk® capsules in primary biliary cirrhosis can be continued indefinitely.

In patients with primary biliary cirrhosis, in rare cases the clinical symptoms may worsen at the beginning of treatment, e.g. the pruritus may increase. Should this occur, the therapy with one Ursofalk® capsule daily should be continued and the dosage gradually increased (by 1 capsule daily each week) until the dose indicated in the dosage scheme is reached.

If you have the impression that the effect of Ursofalk® capsules is too strong or too weak, please talk to your doctor.

**If you have taken more Ursofalk® capsules than you should:**
In general, overdosage is unlikely because the absorption of ursodeoxycholic acid decreases with increasing doses and therefore more is excreted with the faeces.

As a result of the specific properties of ursodeoxycholic acid in Ursofalk® capsules, diarrhoea may occur in the event of overdose.
If diarrhoea occurs, the dose must be reduced and if the diarrhoea is persistent, the doctor must be informed.

No specific countermeasures are necessary; the consequences of diarrhoea should be treated symptomatically with restoration of fluid and electrolyte balance.

**If you have taken too little Ursofalk® capsules or have forgotten to take any at all:**
Do not take more capsules the next time, but just continue the treatment with the prescribed dose.

**Effects when the treatment with Ursofalk® capsules is stopped:**
Always ask your doctor first before you decide to interrupt treatment with Ursofalk® capsules, or stop them prematurely because – for example – side effects have occurred.

## 4. Possible side effects

Like all medicines, Ursofalk® capsules can have side effects.

The evaluation of undesirable effects is based on the following frequency data:

**Very common:**
occurring in more than 1 in 10 patients treated
**Common:**
occurring in more than 1 in 100 patients treated
**Uncommon:**
occurring in more than 1 in 1000 patients treated
**Rare:**
occurring in more than 1 in 10,000 patients treated
**Very rare:**
occurring in 1 case in 10,000 patients treated or fewer, including isolated cases

**Gastrointestinal side effects:**
In clinical trials, reports of pasty stools or diarrhoea during ursodeoxycholic acid therapy were common.
Very rarely, severe right-side upper abdominal pain has occurred during the treatment of primary biliary cirrhosis.

**Hepatobiliary disorders:**
During treatment with ursodeoxycholic acid, calcification of gallstones can occur in very rare cases.
During therapy of the advanced stages of primary biliary cirrhosis, in very rare cases decompensation of the hepatic cirrhosis has been observed, which partially regressed after the treatment was discontinued.

**Hypersensitivity reactions:**
Very rarely, urticaria (nettle rash) can occur.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## 5. Storing Ursofalk® capsules

Keep medicines out of the reach and sight of children.
Do not store above 25 °C.

Do not use after the expiry date as stated on the carton and on the blister strips.

## Date of the information:

October 2003

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