PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Ursofalk 500

Film-coated tablets

Active ingredient:
Each **Ursofalk 500** tablet contains: 500 mg ursodeoxycholic acid.

For the list of the additional ingredients see section 6.

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

The medicine is intended for the symptomatic treatment of primary inflammation of the biliary tract, in patients who do not suffer from decompensated liver cirrhosis.
Therapeutic group: bile acids.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (bile acids such as ursodeoxycholic acid), or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6).
- You have an acute inflammation of the gallbladder or biliary tract.
- You have an obstruction of the biliary tract (blockage of the common bile duct or cystic duct).
- You have frequent, cramp-like upper abdomen pain (biliary colic).
- Your doctor said that you have calcified gallstones (visible in an imaging test).
- Your gallbladder is not functioning properly.

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

Special warnings regarding the use of the medicine

- Consult with your doctor or pharmacist before using Ursofalk tablets.
- In rare cases, symptoms of primary inflammation of the biliary tract (such as itching) may worsen at the beginning of the treatment. If this happens, please refer to your doctor and consult him about reducing your initial dosage.
- If you suffer from diarrhea, inform the doctor immediately, as this could require reducing the dosage or discontinuing treatment with the medicine.

Children and adolescents

Primary inflammation of the biliary tract is very rare in children and adolescents; therefore, no information is available regarding the safety and efficacy of using this medicine in children and adolescents.

Tests and follow-up

- Before starting to use the medicine, perform a pregnancy test (see also "Pregnancy, breastfeeding and fertility" below).
- During the first three months of treatment, your doctor will refer you for liver function tests every 4 weeks. Afterwards, monitoring will be performed at 3 month intervals.

Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Cholestyramine, colestipol (to lower blood lipids level) or antacids containing aluminium hydroxide and/or aluminium oxide. These medicines bind ursodeoxycholic acid in the intestine and prevent its absorption, which reduces its effectiveness. If you must take a medicine containing one of these ingredients, it should be taken at least two hours before or two hours after taking Ursofalk.
- Ciprofloxacin, dapsone (an antibiotic), nitrendipine (used to treat high blood pressure) and other medicines that are metabolized in a similar way. Ursofalk **may reduce the effect of these medicines**. Your doctor may need to change their dosage.
- Ciclosporin (suppresses the activity of the immune system) – Ursofalk may affect the absorption of ciclosporin from the intestine. If you are being treated with ciclosporin, your doctor should check the level of ciclosporin in your blood and adjust the dosage if necessary.
- Rosuvastatin (for treatment of high cholesterol and related conditions) – Ursofalk may affect the activity of the medicine.
- Hormonal medicines containing estrogen (such as contraceptive pills) or certain medicines for lowering blood cholesterol and lipids (such as clofibrate). These medicines increase the formation of gallstones and in some cases may affect the activity of Ursofalk. Consult with the doctor about this.

Use of the medicine and food

The medicine may be taken with no regard to meal times.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy, consult a doctor before using this medicine.

- **Pregnancy:** do not use this medicine during pregnancy, unless the doctor has decided that it is absolutely necessary.
- **Women who may become pregnant:** even if you are not pregnant, you should discuss this possibility with your doctor. Before starting the treatment with Ursofalk, you should perform a pregnancy test and consult the doctor regarding suitable contraceptive methods.
- **Breastfeeding:** tell your doctor if you are breastfeeding or if you are planning to start breastfeeding soon.

Driving and use of machinery

No particular precautions are necessary.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen with the medicine. The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

During the first 3 months of treatment, you should take the medicine in divided doses during the day. As the liver function tests improve, the total daily dose may be taken once a day in the evening.

Body weight (kg)	Daily dose (mg/kg body weight)	Ursofalk 500 mg film-coated tablets			
		First 3 months			**Afterwards**
		Morning	Midday	Evening	Evening (once daily)
47 – 62	12 – 16	½	½	½	1½
63 – 78	13 – 16	½	½	1	2

79 – 93	13 – 16	½	1	1	2½
94 – 109	14 – 16	1	1	1	3
Above 110		1	1	1½	3½

Use in the elderly: there is no evidence that any change in the accepted dosage is needed; however, the relevant precautions should be taken into account.

Use in children and adolescents: there is no age limit to the use of Ursofalk. The administration of the medicine is based on the body weight and medical condition.

Do not exceed the recommended dose.

Duration of treatment
In certain cases, the treatment with the medicine may be continued indefinitely.

How to take the medicine
Swallow the tablets with a glass of water.
If you find it difficult to swallow, Ursofalk capsules are available – please refer to the doctor and consult with him.
Crushing/halving/chewing:
The tablets can be halved according to the score line.
Do not crush or chew the tablets, as the contents of the tablet have a bitter taste which is masked by the coating. No additional information is available regarding crushing/grinding.
Make sure to take the medicine regularly.
If you feel that the effect of the medicine is too strong or too weak, consult the doctor or pharmacist.

If you accidentally took a higher dosage
An overdose may cause diarrhea. If you are suffering from prolonged diarrhea, refer to the doctor immediately. If you suffer from diarrhea, make sure to drink enough liquids, to restore the salt and fluid balance.
If you took an overdose or if a child accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the intended time, do not take a double dose the next time, but rather continue the treatment according to the prescribed dosage and times.
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your state of health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine
Always consult the doctor and discuss the consequences, before you decide to interrupt the continuity of treatment or end the treatment early. The medicine helps to gain control of the medical condition, but does not cure it.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects
As with any medicine, using Ursofalk may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

Serious and very rare side effects (occur in less than one user out of 10,000):
- **Immediately stop using the medicine and refer to the doctor if** there is a significant worsening of the liver cirrhosis. After discontinuing treatment, there may be a partial improvement.

- **Refer immediately to a doctor or to a hospital emergency room if** you suffer from severe right-sided upper abdominal pain.

Additional side effects

Common side effects (occur in 1-10 users out of 100):
- Soft stool and/or diarrhea. If you suffer from diarrhea, **inform the doctor immediately**, as it may be necessary to reduce the dosage or discontinue treatment with the medicine.

Very rare side effects (occur in less than 1 user out of 10,000):
- Gallstone calcification due to build-up of calcium. There are no additional symptoms of this, but it can be seen in tests.
- Urticaria (hives).

Side effects with unknown frequency (effects whose frequency has not yet been determined):
- Itching.
- Nausea, vomiting.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?
- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C.
- Do not discard medicines via wastewater or household waste. Consult a pharmacist on how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. Additional information
- **In addition to the active ingredient, the medicine also contains:**
  Cellulose microcrystalline, povidone K 25, crospovidone, talc, hypromellose, magnesium stearate, silica colloidal anhydrous, polysorbate 80, macrogol 6000.

- **What does the medicine look like and what does the package contain?**
  White, oblong tablets with a score line on both sides, in a blister pack of 50 or 100 tablets. Not all package sizes may be marketed.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301, Israel.

Manufacturer: Dr Falk Pharma GmbH, Freiburg, Germany.ד

Registration number of the medicine in the national drug registry of the Ministry of Health: 150-68-33832

Revised in July 2025.