Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Ursofalk® 500

Film-coated Tablets

Active ingredient:
Each tablet of **Ursofalk 500** contains: Ursodeoxycholic acid 500 mg.
For a list of inactive ingredients, please see section 6.
Read this entire leaflet carefully before using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
This medicine has been prescribed for the 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 to yours.

1. What is the medicine intended for?

This medicine is intended for the symptomatic treatment of primary biliary cirrhosis, in patients without decompensated liver cirrhosis.
Therapeutic group: Bile acids.

2. Before you take the medicine

Do not use the medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient (bile acids) or to any of the other ingredients this medicine contains (for a list of inactive ingredients, please see section 6).
- Do not use if you suffer from acute inflammation of the gall bladder and/or biliary tract.
- Do not use if you suffer from an obstruction of the biliary tract.
- Do not use if you suffer from biliary colic (may be manifested by frequent pain/cramps in the upper abdomen).
- Do not use if you suffer from calcified gallstones.
- Do not use if your gall bladder does not contract properly.

Special warnings regarding the use of this medicine

- This medicine should be used under medical supervision (see also 'Tests and follow up' in section 3).
- If you have suffered in the past from any of the conditions mentioned in the section 'Do not use the medicine if'- inform your doctor.
- If you suffer from diarrhea during the treatment, inform your doctor immediately, as your doctor may decide to reduce the dosage of the medicine or to stop its use.
- In rare cases, some of the symptoms of biliary cirrhosis (such as itching) may worsen at the beginning of the treatment. In such a case, refer to the doctor, who might recommend continuing the treatment with a lower daily dose (see also section 3 'Attention').
- If you are sensitive to any type of food or medicine, inform the doctor before taking the medicine.

Possible interactions with other medicines taken concomitantly with Ursofalk:

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Cholestyramine and colestipol (to lower blood lipids) as well as antacids containing aluminium: If you must take these medicines, they have to be taken at least two hours before taking Ursofalk or two hours afterwards.
- Ciprofloxacin (antibiotic), dapsone (antibiotic) and nitrendipine (for reduction of blood pressure) - Ursofalk may reduce the effect of these medicines. Their dosage may need to be altered.
- Ciclosporin (immunosuppressant) - Ursofalk may affect the absorption of the medicine. The doctor will check its blood concentration and adjust the dosage if necessary.
- Rosuvastatin (for reduction of cholesterol) – Ursofalk may affect the activity of the medicine.
- Birth control pills and certain medicines for reduction of cholesterol and blood lipids such as clofibrate: In certain cases these medicines may affect the activity of Ursofalk. Consult the doctor regarding this.

Use of this medicine and food
The medicine may be taken regardless of meal times.

Pregnancy and breastfeeding
If you are planning a pregnancy, are pregnant or are breastfeeding, consult your doctor before usage.

- This medicine should not be used in pregnant women, unless the doctor decided it is absolutely necessary. Women that may become pregnant should use contraceptives as recommended by the doctor.
- A small amount of the medicine passes into breast milk. Consult the doctor if you are breastfeeding.

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

3. How to use this medicine?
Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure.
The dosage and the manner of treatment will be determined by the doctor only.
Use this medicine at set intervals as determined by the attending doctor.
The dosage will be determined by the doctor according to your age, severity of your disease and your weight.

Swallow the tablets with water regardless of meal times.
The tablets can be halved using the scored line.
Do not crush the tablets as there is no information about crushing.
Do not chew the tablets.

Do not exceed the recommended dose.

Attention! In rare cases some of the symptoms of biliary cirrhosis (such as itching) may worsen at the beginning of the treatment. In such a case, treatment can be continued with a lower daily dosage according to the doctor's instructions . After that, gradually (usually every week) your doctor will increase the dosage up to the required dosage.

Tests and follow up

In the first three months of the treatment, liver functions tests should be performed every four weeks. Afterwards, it is recommended to perform the test every 3 months.

If you have accidentally taken a higher dosage diarrhea may occur. Refer to your doctor immediately if you suffer from persistent diarrhea. If you are suffering from diarrhea, make sure you drink enough liquids to restore your electrolyte and fluid balance.
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the set time, do not take a double dose the next time, but rather continue the treatment with the dosage and at the times that were determined.

Continue with the treatment as recommended by your doctor.
Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects

Like any medicine, the use of Ursofalk may cause side effects in some users. If the side effects persist or are bothersome or get worse, consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Common side effects (appear in 1-10 users out of 100):

- Soft stools and/or diarrhea (see also section: 'Special warnings regarding the use of this medicine').

Very rare side effects (appear in less than one user out of 10,000):

- Severe right-sided upper abdominal pain, worsening of liver cirrhosis which partially improves after treatment is discontinued.
- Calcification of gallstones.
- Urticaria (hives).

In any case you experience side effects that are not mentioned in this leaflet, or if you feel a change in your general feeling, consult with your doctor immediately!

Side effects and drug interactions in children:
Parents must inform the attending doctor about any side effect, as well as any additional medicine being given to the child.
See above for detailed side effects and drug interactions.

Side effects may be reported to the Ministry of Health by clicking on the link "reporting side effects following drug treatment" on the Ministry of Health homepage

(www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a 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^{O}C.

6. Additional information

- **In addition to the active ingredient, this medicine also contains the following inactive ingredients:**
  Magnesium stearate, polysorbate 80, povidone K 25, microcrystalline cellulose, silica colloidal anhydrous, crospovidone, talc, hypromellose, macrogol 6000.

- **What does the medicine look like and what does the package contain?**
  White tablets with a scored line in blisters, packs of 50 or 100 tablets per box. (Not all package sizes may be marketed).

Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301.
Manufacturer: Dr. Falk Pharma, Freiburg, Germany.

Medicine registration number in the National Medicine Registry of the Ministry of Health: 150 68 33832

This leaflet was checked and approved by the Ministry of Health in February 2016.