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

The medicine is dispensed with a doctor's prescription only

Ursolit 100, 300 Tablets

The active ingredient:

Ursolit 100:

Ursodeoxycholic acid 100 mg.

Ursolit 300:

Ursodeoxycholic acid 300 mg

For inactive ingredients see section 6. See also section 2 "Important information about some ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other 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 medical condition is similar.

1. What is the medicine intended for?

The medicine is intended for the dissolution or reduction in size of gallstones composed of cholesterol, and for treatment of certain chronic liver diseases.

Therapeutic class: Bile acids.

2. Before using the medicine:

☒ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (bile acids) or any of the additional components the preparation contains (for a list of inactive ingredients, see section 6).
- You are suffering from an inflammatory exacerbation of the gallbladder and/or biliary tract.
- You are suffering from biliary obstruction.
- You are suffering from a severe liver disease (other than primary biliary cirrhosis).
- You are suffering from a stomach ulcer.
- You are suffering from calcified gallstones.
- Your gallbladder is not contracting properly.
- You are suffering from an inflammation of the intestines.
- You are suffering from biliary colic frequently (usually characterized by pain in the upper right side of the abdomen).

Special warnings regarding the use of the medicine:

- The medicine should be used under medical supervision (see also "tests and follow-up" in section 3).
- If you have previously suffered from any of the conditions mentioned in the "Do not use this medicine if" section - inform your doctor.
- In case you are suffering from diarrhea during the treatment, inform the doctor immediately, since he may decide to reduce the dosage or discontinue the treatment.
- In rare cases, some symptoms of biliary cirrhosis (such as itching) may worsen in the beginning of the treatment. In such a case, you should contact the doctor, who may recommend to continue the treatment with a lower daily dose (see also "Attention!" in section 3).
- If you are sensitive to any type of food or medicine, inform your doctor before starting treatment with this medicine.

☒ If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

Especially if you are taking:

- Colestyramine and colestipol (for lowering lipid blood levels), active charcoal and aluminum-containing antacids. If you must take these medicines, take them at least two hours before or two hours after taking Ursolit.
- Ciprofloxacin (antibiotics), dapsone (antibiotics) and nitrendipine (for lowering blood pressure) - Ursolit may reduce the effect of these medicines. Their dosage may need to be changed.
- Ciclosporine (immunosuppressant) - Ursolit may affect this medicine's absorption. The doctor will test the blood ciclosporine concentration and adjust the dosage as needed.
- Rosuvastatin (for lowering cholesterol levels) - Ursolit may affect the medicine's action.
- Contraceptive pills, estrogen and certain medicines for lowering blood cholesterol and lipids such as clofibrate. In certain cases these medicines may affect Ursolit's action. Consult with the doctor about this.

☒ Use of the medicine and food

The medicine should be taken with or after a meal.

A low-cholesterol diet may contribute to the treatment's success.

☒ Pregnancy and breastfeeding

If you are planning pregnancy, are pregnant or

breastfeeding, consult a doctor before using the medicine.

- Do not use the medicine during pregnancy unless the doctor has decided that it is absolutely necessary. Women who may become pregnant should use contraceptives as will be recommended by the doctor.

☒ Breastfeeding

A small amount of the medicine passes into breastmilk. If you are breastfeeding, consult with your doctor.

☒ Driving and operating machinery

Ursolit does not affect the ability to drive or operate machinery.

☒ Use in children

This medicine is not intended for babies and children.

Safety of use in children has not been established.

☒ Important information about some ingredients of the medicine

The preparation contains lactose and may cause an allergic reaction in people who are sensitive to lactose. Each tablet of Ursolit 100 contains 75 mg lactose monohydrate.

Each tablet of Ursolit 300 contains 100 mg lactose monohydrate.

3. How should you use the medicine?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor.

The doctor may recommend you to use Ursolit for up to 24 months, depending on the size of the gallstones. You should continue treatment with Ursolit for 3 months after the gallstones have been dissolved.

This medicine should be used at set intervals as determined by the attending doctor.

The dosage will be determined by the doctor according to your age and weight and disease severity. The tablets may be halved or pulverized as necessary.

Do not exceed the recommended dose.

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

Tests and follow-up

During the first three months of treatment liver functions tests should be performed every 4 weeks. Afterwards, it is recommended to perform the test every 3 months.

If you accidentally take a higher dosage, diarrhea is possible. If you are suffering from prolonged diarrhea, contact the doctor immediately.

If you have diarrhea, be sure to drink enough fluids in order to restore your salt-fluid balance.

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

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

4. Side effects:

As with any medicine, using Ursolit may cause side effects in some users. If the side effects do not go away, if they are bothersome or if they worsen, consult your doctor. Do not be alarmed when reading the list of side effects. You may not experience any of them.

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

- Soft stool and/or diarrhea (see also "Special warnings regarding the use of the medicine" in section 2).

Very rare side effects (occur in less than 1 out of 10,000 patients):

- Severe pain in the upper right side of the abdomen, worsening of cirrhosis which partially improves upon discontinuation of treatment.
- Gallstones calcification.
- Urticaria (hives).

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Nausea.
- Vomiting.
- Itching.

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 your 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://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 kept in a closed place out of the reach 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) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 25°C.

6. Additional information:

- In addition to the active ingredient the medicine also contains:

Ursolit 100:

Lactose, Carboxymethyl-Cellulose Calcium, Maize Starch, Povidone 25, Magnesium stearate

Ursolit 300:

Maize Starch, Lactose, Povidone 25, Magnesium stearate, Colloidal Silicone Dioxide

- What does the medicine look like and what are the contents of the package?

Ursolit 100: Round, biconvex, scored, white tablets. Blister pack of 60, 100, 500 and 1000.

Not all package sizes may be marketed.

Ursolit 300: Round, biconvex, scored, white tablets. Blister pack of 30 tablets.

- License holder/manufacturer and the address: CTS Chemical Industries Ltd., Kiryat Malachi.
- This leaflet was checked and approved by the Ministry of Health in: September 2017
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: Ursolit 100: 192520542, Ursolit 300: 586326923