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
Inactive ingredients and allergens in the preparation – see the subsection "Important information about some of the ingredients of the medicine" and section 6.
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.
Ursodeoxycholic acid affects the bile composition, so that the gallstones dissolve.
The effect of ursodeoxycholic acid in some chronic liver diseases results from a variety of mechanisms, such as a protective activity on liver cells and effect on the immune system.

LFL 622 01/23

2. Before using the medicine

☒ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (bile acids) or to any of the additional components the medicine contains (for a list of inactive ingredients, see section 6).
- You suffer from an inflammatory exacerbation of the gallbladder and/or biliary tract.
- You have a biliary obstruction or stenosis.
- You suffer from a gastric or intestinal ulcer.
- You suffer from calcified gallstones.
- Your gallbladder is not contracting properly.
- You suffer from biliary colic (can manifest in pain/frequent cramps in the upper abdomen).

❗ Special warnings regarding the use of the medicine

- The medicine should be used under medical supervision (see also "Tests and follow-up" later in this section).
- 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).
- Women who are using Ursolit to dissolve gallstones, should not take hormonal contraceptive preparations as the hormones in these contraceptives can increase the formation of gallstones.
- In the final stage of a biliary tract infection, in very rare cases, the function of the liver may be greatly reduced. The liver function will partly recover after stopping the treatment.

❗ Tests and follow-up
During the first three months of treatment, liver function tests should be performed every 4 weeks. Afterwards, it is recommended to perform the test every 3 months. Apart from diagnosing the response to treatment in patients with liver diseases, this follow-up will allow early detection of liver impairment.
When the treatment with the preparation is intended for dissolving or reducing the size of gallstones: cholecystography should be performed orally 6-10 months from the beginning of the treatment, in order to assess the progress of the treatment in dissolving gallstones and in order to diagnose possible calcification of the stones.

❗ 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:

- Colestyramine and colestipol (for lowering lipid blood levels), and aluminum-containing antacids. If you must take these medicines, take them at least two hours before or two hours after taking Ursolit.
- Ciprofloxacin (an antibiotic), dapsone (an antibiotic), 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 its blood 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.
❗ Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, may be pregnant or are planning to become pregnant or to breastfeed, consult a doctor before using.
Pregnant women should not use this medicine 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. During treatment with the medicine, possible contraceptives are the non-hormonal type, such as barrier contraceptives, or contraceptive pills with a low dose of estrogen. However, when the treatment is intended for dissolving gallstones, only non-hormonal contraceptives can be used, as the hormones in the hormonal contraceptives may increase the formation of gallstones.
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 of the ingredients of the medicine
This preparation contains lactose. If you have been told by the doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined by the doctor.
The dosage will be determined by the doctor according to your age, disease severity and weight.
The doctor may recommend you to use Ursolit for up to 24 months of treatment, 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 treating doctor.
Do not exceed the recommended dose.
The tablets may be halved or pulverized.
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.
If you accidentally took 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 to a hospital emergency room 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. Continue the treatment at the prescribed dose and times.
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 <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any other questions regarding the 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. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Common side effects – side effects that occur in 1-10 users out of 100:

- Soft stool and/or diarrhea

Very rare side effects – side effects that occur in less than 1 user out of 10,000:

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

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.
<u>Reporting side effects</u>
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.) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.

6. Additional information:

In addition to the active ingredient, the medicine also contains:
Ursolit 100:
Lactose Monohydrate, Carboxymethyl-Cellulose Calcium, Maize Starch, Povidone, Magnesium stearate
Ursolit 300:
Maize Starch, Lactose Monohydrate, Povidone, 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. The medicine is marketed in a blister pack of 60, 100, 500 and 1,000 tablets. Not all package sizes may be marketed.
Ursolit 300: Round, biconvex, scored, white tablets. The medicine is marketed in a blister pack of 30 tablets.
Marketing authorization holder/manufacturer and the address: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi, Israel.
This leaflet was revised in 01/2023 in accordance with the Ministry of Health guidelines.
Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Ursolit 100: 019-25-20542
Ursolit 300: 058-63-26923