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.

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 ingredients the medicine contains (for a list of inactive ingredients, see section 6).
- You have an acute inflammation of the gallbladder or biliary tract.
- You have a biliary tract obstruction or stenosis (blockage of the common bile duct or cystic duct).
- You suffer from a gastric or intestinal ulcer.
- You suffer from calcified gallstones (seen in imaging test).
- Your gallbladder is not contracting properly.
- You have frequent, cramp-like upper abdomen pain (biliary colic).

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

- 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 the doctor may decide to reduce the dosage of the medicine or discontinue it.
- 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 inflammation, 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

- Before starting to use the medicine, you should have a pregnancy test (see also "Pregnancy, breastfeeding and fertility" below).
- During the first three months of treatment, liver function tests should be performed every 4 weeks. Afterwards, monitoring will be performed every 3 months. Apart from diagnosing the response to treatment of 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 blood fat levels) or antacids containing aluminum hydroxide and/or aluminum oxide. These preparations bind ursodeoxycholic acid in the intestine and prevent its absorption, which reduces its effectiveness. If you must take a medicine that contains any of these ingredients, it must be taken at least two hours before or two hours after taking Ursolit.
- Ciprofloxacin (an antibiotic), dapsone (an antibiotic), nitrendipine (used for the treatment of high blood pressure) and other medicines that are metabolized in a similar way. Ursolit **may reduce the effect of these medicines**. Their dosage may need to be changed.
- Ciclosporin (suppresses the activity of the immune system) – Ursolit may affect the absorption of the medicine 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) – Ursolit may affect the activity of this medicine.
- Hormonal medicines that contain estrogen (such as contraceptive pills) or certain medicines for lowering blood cholesterol and fats (such as clofibrate). These medicines increase the formation of gallstones and in some cases may affect the activity of Ursolit. 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 use.

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 Ursolit, you should have a pregnancy test and consult the doctor regarding suitable contraceptives. 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.

Breastfeeding: a small amount of the medicine passes into breastmilk. Consult the doctor if you are breastfeeding or planning to start breastfeeding soon.

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 instructions. 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 if 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 every time 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 suffer from any of them.

Serious and very rare side effects (occur in less than 1 user out of 10,000):

- **Immediately stop using the medicine and refer to the doctor if** there is a significant worsening of your liver cirrhosis (especially during treatment of primary biliary cholangitis). After discontinuing treatment, there may be a partial improvement.
- **Refer immediately to the doctor or to a hospital emergency room if** you suffer from severe right-sided upper abdominal pain (especially during treatment of primary biliary cholangitis).

Additional side effects

Common side effects – effects that 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 – effects that 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 will show up 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 your doctor.

Reporting side effects

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 11/2025 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: 019-25-20542-00

Ursolit 300: 058-63-26923-00

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