

Urocit-K® 10 mEq Extended-release tablets

The active ingredient and its quantity:
Every extended-release tablet contains:
Potassium citrate 1080 mg

For the list of excipients, 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, refer to the doctor or pharmacist.

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

The medicine is intended for adults above 18 years of age.

1. What is the medicine intended for?

- For treatment of renal tubular acidosis with calcium stones
- For treatment of calcium oxalate stones (nephrolithiasis) as a result of low levels of citrate in the urine, for any reason
- For treatment of uric acid stones with or without calcium stones

2. Before Using the Medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (potassium citrate) or one of the other ingredients of the medicine. The active ingredient appears at the beginning of the leaflet before section 1 and the inactive ingredients are listed in section 6.
- You have hyperkalemia (excess potassium in the blood) or conditions which increase the risk of hyperkalemia, such as: chronic kidney failure, unbalanced diabetes, acute dehydration, strenuous exercise for people who are not fit, adrenal insufficiency, extensive tissue breakdown or taking "potassium-sparing" diuretics (such as triamterene, spironolactone or amiloride). This is because another increase in blood potassium concentration may cause cardiac arrest.
- You have gastrointestinal problems that may delay or arrest the tablet from passing through the gastrointestinal tract, such as: delayed gastric emptying, esophageal compression, intestinal obstruction or stricture or if you are taking anticholinergic medicines.
- You have a peptic ulcer.
- You have an active urinary tract infection.
- You suffer from renal insufficiency.

Special warnings regarding the use of this medicine:

Before starting treatment with Urocit-K tell your doctor if:

- You suffer from a potassium excretion problem. Urocit-K may cause hyperkalemia (excess potassium in the blood) and cardiac arrest. Hyperkalemia may be life threatening, can develop quickly and without symptoms. Avoid using Urocit-K in patients who suffer from chronic kidney failure or any other condition that damages potassium excretion (such as: severe myocardial damage or heart failure). The doctor will perform periodic tests (see section "tests and follow-up").
- Use of the medicine may cause different levels of damage to the gastrointestinal mucosa. If signs such as severe vomiting, abdominal pain or gastrointestinal bleeding appear, stop using the medicine immediately and refer to a doctor right away.

Tell the doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements. Especially if you are taking:

- "Potassium-sparing" diuretics such as: triamterene, spironolactone or amiloride. Using these medicines concomitantly with Urocit-K may cause severe hyperkalemia, therefore do not use them simultaneously (see section "Do not use this medicine").
- Medicines that slow gastrointestinal transit time, such as anticholinergics (see section "Do not use this medicine"). Using these medicines with Urocit-K may increase the gastrointestinal irritation caused by potassium salts.
- "Digitalis" type medicines.

Use of this medicine and food:

- Take with meals or within 30 minutes of food.
- During the treatment with this medicine, avoid eating food that contains high quantities of salt and adding salt to food. Also, drink a lot during the treatment with the medicine.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, consult your doctor or pharmacist before using medicines.

It is unknown if Urocit-K can harm the fetus or if the medicine passes into breast milk, and therefore use of the medicine in pregnant and breastfeeding women is according to doctor's instructions only and only after the doctor has decided if it is necessary.

Use in children:

Security and efficacy of the medicine Urocit-K were not tested in children.

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 method of treatment will be determined by your doctor only. The usual recommended dosage is: Severe citrate deficiency in the urine:

The initial dosage is 60 mEq daily. Take 3 tablets twice daily or 2 tablets 3 times daily. According to the results of the urine tests, your doctor will decide whether to change the dosage.

Mild to moderate citrate deficiency in the urine:

The initial dosage is 30 mEq daily. Take one tablet 3 times daily. According to the results of the urine tests, your doctor will decide whether to change the dosage.

Do not exceed the recommended dose.

- Drink a lot of water.
- Do not crush, chew or suck the tablet.
- Patients may see parts of the tablet that do not dissolve in their stools.
- Consult the doctor if it is difficult for you to swallow the tablet or if you feel the tablet gets stuck in your throat.

Tests and follow-up:

Your doctor will perform urine tests at the beginning of the treatment, after changing the dosage and regularly every several months. Also, your doctor will perform periodic ECG tests. Your doctor will check the blood electrolyte levels (sodium, potassium, chloride and carbon dioxide), blood creatinine and a full blood count every four months and at a higher frequency in patients with heart disease, kidney disease or acidosis. Your doctor will decide how to continue treatment according to the test results.

If you have accidentally taken a higher dosage, you may suffer from hyperkalemia. Usually, hyperkalemia is without symptoms and is identifiable by blood test and by changes in ECG. Side effects that occur during the advanced stages of hyperkalemia include muscle paralysis and cardiac arrest. 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 required time, do not take a double dose. Take the next dose at the regular time and consult your doctor.

Continue treatment as recommended by your doctor. Even if there is an improvement in your medical condition, do not stop the treatment with the 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 every medicine, the use of Urocit-K may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop treatment with the medicine and refer to a doctor immediately if:

- you suffer from severe vomiting, abdominal pain or gastrointestinal bleeding (for example if your stools are dark red or black), these side effects may indicate bowel perforation or obstruction.

Additional side effects:

Abdominal discomfort, nausea, vomiting, diarrhea and soft stools. These side effects result from irritation of the gastrointestinal tract and can be reduced by taking the medicine with food or reducing the dosage.

If a side effect appears, if one of the side effects worsens or when you suffer from a side effect that was not mentioned in the leaflet, consult the doctor or pharmacist.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the home page of the Ministry of Health's website (www.health.gov.il) directing to the online form for reporting side effects, or via the following link: <https://sideeffects.health.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 and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your 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.
- Store below 25° C.
- After first opening the bottle it can be used until the expiry date of the medicine.
- Store in a tightly closed container.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains: Carnauba Wax and Magnesium Stearate

What the medicine looks like and what the package contains:

Urocit-K 10mEq tablets are uncoated, yellowish colored, elliptical shaped, with "10" debossed on one side and "MISSION" on the other.

The tablets are available in plastic bottles of 100 units.

Registration holder and address: Pharmabest Import (2003) Ltd., 14 Shenkar St., Petah Tikva 491394.

Name of manufacturer and address: Mission Pharmaceutical Company, Boerne, Texas, USA.

Drug registration number at the national medicines registry of the Ministry of Health: 156-56-34526-00

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