

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine is to be supplied by physician's prescription only

Uralyt-U, Granules

Active ingredient:

Each measuring spoon with 2.5 g of granules contains:

Potassium Sodium Hydrogen Citrate 2.427 g (6.6:3.5)

Equivalent to the following values:

Potassium 11mEq
Sodium 11mEq
Citrate 27mEq

For the full list of inactive ingredients: see section 6 "Additional Information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

Uralyt-U belongs to the class of medicines causing alkalization of the urine.

What is this medicine intended for?

This medicine is used to dissolve uric acid stones and to prevent further stone formation in the urinary tract.

Treatment with this medicine is part of prophylactic therapy including appropriate diet, increased fluid consumption etc.

Before using this medicine

Do not use this medicine if:

- You are sensitive to any of the ingredients that this medicine contains (see "Additional Information")
- You suffer from acute or chronic renal failure
- You are on a sodium free diet
- You suffer from metabolic alkalosis
- You have high levels of potassium in the blood
- You suffer from chronic urinary tract infections caused by urea degrading bacteria

Special warnings regarding the use of this medicine

- Before starting treatment with Uralyt-U, any diseases or conditions which may cause the formation of uric acid stones need to be ruled out.
- Before starting treatment with Uralyt-U, blood levels of electrolytes, renal function and pH of the urine should be examined if RTA (renal tubular acidosis) is suspected. In particular in elderly, patients with renal function problems or patients taking medicines listed in section "If you are taking or have recently taken other medicines".
- Caution is required with patients suffering from a severe impairment of liver function.
- The orange yellow S (E 110) ingredient may cause an allergic reaction.
- While being treated with this medicine, drink plenty of water.

If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist. In particular inform the physician or the pharmacist if you are taking:

- Medicines elevating the extracellular potassium concentration, reduce the effect of cardiac glycosides, while reduction in the extracellular potassium concentration leads to arrhythmias during treatment with cardiac glycosides.
- Blood pressure medicines such as: aldosterone antagonist, AT II antagonist, potassium sparing diuretics, Ace Inhibitors.
- Medicines for chronic pain management such as NSAIDs (non-steroidal pain relief medicines) and peripheral pain relief medicines, reduce urinary potassium secretion.
- Medicines containing aluminum, such as certain medicines for the treatment of heartburn. Since Uralyt-U also contains citrate, concomitant intake may cause increased aluminum absorption. Therefore, they should be taken with an interval of at least two hours.
- For patients on low sodium diet, it must be noted that 1.0 gram of Uralyt-U contains 0.172 g or 4.4 mmol sodium.

Children

The medicine is not intended for children under the age of 12, since there is no sufficient experience in this population.

Using Uralyt-U and food

Take the medicine after the meal.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, you should consult a physician before taking this medicine.

Driving and using machines

Uralyt-U has no known effect on your ability to drive or operate machines.

Important information about some of the medicine's ingredients

Uralyt-U contains orange yellow S (E 110) which may cause allergic reactions such as asthma. An allergic reaction will be more common in people reacting to acetyl salicylic acid.

How should you use the medicine?

Always use according to the physician's Instructions.

You should check with the physician or the pharmacist if you are not sure.

For dissolving uric acid stones

- The standard dosage is 4 measuring spoons per day (10 g per day) divided into 3 doses: one spoon in the morning, one spoon at noon and two spoons in the evening after the meal.
- Urine pH should be in the range of 6.2-6.8.
- If the measured pH is below the recommended range, increase the daily dosage by half a spoon in the evening.
- If the measured pH is above the recommended range, decrease the dosage by half a spoon in the evening.
- If the pH is within the recommended range, you are taking the dosage suitable for you.

For prevention of the formation of uric acid stones in the urinary tract:

- The standard dosage is 2-3 measuring spoons per day (5-7.5 g) taken in 1 dose in the evening after the meal.
If the pH is low, take 3-4.5 measuring spoons per day (7.5-11.25 g) divided into 2-3 doses during the day after meals.
- Urine pH should be in the range of 6.2-7.4.
- Urine pH should be regularly monitored and the dosage should be adjusted accordingly.
- Dissolve the granules in a glass of water and drink the entire glass.
- Urine test should be performed immediately before taking each dose of Uralyt-U in the morning, at noon and in the evening.
- The test is performed by dipping the test strip in recently collected urine for several seconds. Alternatively, you may hold the test strip with the strip holder against the urine stream while urinating. Immediately compare the change in the strip color with the corresponding color in the test strip manual. Record the result in the designated place provided in the test card inserted into the package.
- Treatment duration: The physician will determine the duration of your treatment. You must complete the treatment recommended by the physician even if your health condition has improved; do not discontinue the treatment without consulting the physician.
- If you feel that the effect of Uralyt-U is too strong or too weak, consult the physician.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to the physician and bring the medicine package with you.

If your renal function is normal, no effects on the metabolism are expected to occur even if you have mistakenly taken a large quantity of Uralyt-U. An overdose may lead to high potassium level (above 5 mmol/L in the plasma) especially in patients suffering from acidosis or renal failure. You can detect an overdose by testing urine pH; the dosage should be adjusted accordingly.

If you forget to take the medicine at the scheduled time, immediately take the forgotten dose; do not take a double dose to compensate for the forgotten dose.

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

Side effects

As with any medicine, Uralyt-U may cause side effects in some patients. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Common side effects:

- Abdominal pain

Rare side effects:

- Diarrhea or nausea

Side effects of unknown incidence:

- The orange yellow S (E 110) ingredient may cause an allergic reaction

If any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.
- Use Uralyt-U within up to 6 months from the date of package opening.
- Do not store at a temperature above 25°C.

Additional information

- In addition to the active ingredient Potassium Sodium Hydrogen Citrate the medicine also contains: Lemon Oil, Yellow Orange S (E 110)
- Each measuring spoon of 2.5 g Uralyt-U contains 2.427 g Potassium Sodium Hydrogen Citrate (6.6:3.5)
- What does the medicine look like and what are the contents of the package: Uralyt-U contains pale orange granules and is supplied in 280 g packs. The packs contain a measuring spoon and pH test strips
- Registration holder and address: MegaPharm Ltd., P.O.B. 519, Hod Hasharon, 4510501
- Manufacturer and address: Madaus, Cologne, Germany
- This leaflet was checked and approved by the Ministry of Health in June 2014
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 063-87-22365