Uralyt-U® Granules for oral solution (potassium sodium hydrogen citrate) Abbreviated Prescribing Information.

Presentation: Uralyt-U® (potassium sodium hydrogen citrate) is available in a form of Granules for oral solution. Each measuring spoonful of granules of 2.5 g contains potassium sodium hydrogen citrate (6:6:3:5) 2.4 g. **Indications:** Dissolution of uric acid stones, for Metaphylaxis (prevention of recurrent formation) of calcium stones and uric acid stones and/or mixed calcium oxalate and uric acid stones or calcium oxalate and calcium phosphate stones. Note: This product should only be used as a part of a general concept of metaphylaxis (e.g. diet, increased fluid uptake etc.). **Posology and method of administration:** Dissolution and metaphylaxis of uric acid stones: In general, it is recommended to take 4 measuring spoonfuls (= 10 g of granules equivalent to 88 mmol of alkali) daily divided into three doses, after meals. One measuring spoonful shall be taken in the morning, 1 measuring spoonful at noon and 2 measuring spoonfuls in the evening. The pH value of the freshly voided urine should be within the range of Uric acid stones: pH 6.2 – 6.8. If the pH value is below the specified range, the daily dose should be increased by half a measuring spoonful of Uralyt-U® (11 mmol alkali) in the evening. If the pH is above the specified range, the daily dose should be reduced by half a measuring spoonful (11 mmol alkali) in the evening. The correct dose has been reached if the pH value of the freshly voided urine, measured before taking the dose of Uralyt-U®, is within the specified range. For metaphylaxis of uric acid stones, regular checks of the urine pH levels are recommended. Metaphylaxis of calcium-containing kidney stones: The recommended daily dose is 2 - 3 measuring spoonfuls (= 5- 7.5 g granules equivalent to 44-66 mmol of alkali) should be taken in a single dose in the evening. If needed, i.e. If the measured pH value is too low, 3 - 4.5 measuring spoonfuls (= 7.5 g - 11.25 g granules equivalent to 66-99 mmol alkali should be taken in 2-3 doses divided over the day, after meals. A neutral pH value should be aimed at. The pH value should not be lower than pH 6.2 and should not exceed pH 7.4. Citrate levels and/or urine pH values should be regularly checked, and the individual dose be adjusted accordingly. **Paediatric Population:** No data are available. **Method of Administration:** The granules should be dissolved in a glass of water and drunk. Measurement of urine pH value: immediately before taking each dose, a test strip of the indicator paper provided in the pack should be wetted with freshly voided urine. The colour of the wet test strip shall then be compared with the colour chart, and the pH value printed below the corresponding colour can be read off. This pH reading as well as the number of measuring spoonfuls of granules taken should be noted in the control calendar. The patient shall bring along this calendar every time he/she visits the doctor. **Contraindications:** In the patient information leaflet it is pointed out to the patient that Uralyt-U® should not be used in cases of impaired renal excretory function, metabolic alkalosis, hyperkalemia, Adynamia episodica hereditaria, chronic urinary tract infections with urea-splitting bacteria (danger of formation of struvite stones), low sodium diet, hypersensitivity to potassium sodium hydrogen citrate, yellow orange S (E 110) or to any of the excipients. Note: The treatment of children less than 12 years of age is not recommended as there is insufficient clinical experience for this age group. **Special warnings and precautions for use:** Before starting treatment, all circumstances or diseases which may be in favor of urinary stones and for which a well-targeted therapy is available (such as adenoma of parathyroid glands, malignancy associated with uric acid stones etc.) should be ruled out. The maximum recommended daily dose is 11.25 g of granules (4.5 measuring spoonfuls). This is equivalent to 1.86 g of potassium and 1.09 g of sodium, i.e., 47.5 mmol potassium and 47.5 mmol of sodium. This should be considered in particular when treating the elderly and in case of concomitant therapy with potassium-saving diuretics, aldosterone antagonists, ACE-inhibitors, angiotensin receptor antagonists, non-steroidal anti-inflammatory drugs or peripheral analgesics. Interaction with these medicinal products can lead to hyperkalemia. Before taking

the first dose, the serum electrolytes should be determined and renal function should be monitored. Moreover, the acid-base status should be checked when renal tubular acidosis (RTA) is suspected. UralytU® should be used with caution in patients with severely impaired liver function. This medicinal product contains the colouring agent yellow orange S (E110) which may induce allergic reactions including asthma in a sensitized person. Allergy is more often seen in people reacting to 2-acetoxybenzoic acid (acetylsalicylic acid). **Interaction with other medicinal products and other forms of interaction:** Any increase in extracellular potassium concentration will weaken the effect of cardiac glycosides, while any decrease will potentiate the arrhythmogenic effect of cardiac glycosides. Aldosterone antagonists, potassium-saving diuretics, ACE inhibitors, angiotensin receptor antagonists, nonsteroidal anti-inflammatory drugs and peripheral analgesics reduce renal potassium excretion. Attention should be paid to the fact that 1.0 g potassium sodium hydrogen citrate contains 0.172 g or 4.4 mmol potassium. When prescribing a low sodium diet, it should be remembered that 1.0 g of potassium sodium hydrogen citrate contains 0.1 g or 4.4 mmol of sodium (equivalent to 0.26 g of sodium chloride). Concomitant administration of substances containing citrate and aluminum can lead to increased aluminum absorption; if such medicines need to be taken, an interval of at least 2 hours must be allowed between taking each kind of product. **Pregnancy and lactation** There are no adequate clinical data from the use of Uralyt-U® in pregnant women. Experimental studies in animals did not indicate any teratogenic or embryotoxic effects. As the active substance is a combination of physiologically occurring substances, Uralyt-U® may be used in pregnancy and lactation under the specified dose recommendations. No indications for harmful effects during pregnancy and lactation have been noted. **Effects on ability to drive and use machines**: Uralyt-U® has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** Side effects' rating was based on the following frequency data: Very common (≥1/10): Not applicable. Common (≥ 1/100 to < 1/10): Mild gastric or abdominal pain. Reporting of suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions according to their local country requirements. **Overdose:** Overdose can lead to Hyperkalemia (potassium-plasma level >5 mmol/l), in particular in patients with simultaneous acidosis or renal failure. Provided that renal function is adequate, there is no likelihood of any unwanted effects on normal metabolic physiological parameters, even after taking doses higher than those recommended, since the excretion of any base excess via the kidney provides a natural regulatory mechanism which ensures maintenance of the acid-base balance. It should be avoided that the specified urine pH range will be exceeded for several days, since considerably elevated pH values are related with an increased risk of phosphate crystallization. On the other hand, the long-term establishment of a marked alkalotic metabolic state shall not be achieved. Inadvertent overdosage can be corrected at any time by reducing the dose: if necessary appropriate measures for the treatment of metabolic alkalosis may be considered.

Special precautions: Do not store above 30°C.

Reference: SmPC Approved in Gulf, Levant & Iraq. Last revision of the text: April 2015

Date of Document: 13th of November 2022.

Full prescribing information is available upon request

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