SCHEDULING STATUS

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1 NAME OF THE MEDICINE

URALYT®-U granules

2 QUALITIVE AND QUANTITIVE COMPOSITION

One measuring spoon (2,5 g granules) contains:

2,43 g potassium sodium hydrogen citrate (6:6:3:5)

Equivalent to:

11 mEq potassium

11mEq sodium

27 mEq citrate

Sugar free

For full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pale orange granules with an aromatic odour and a salty taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. To dissolve uric acid calculi in the urinary tract and to prevent further stone formation.
2. To alkalinise the urine during treatment with uricosuric agents and during cytostatic therapy.

4.2 Posology and method of administration

To ensure success it is essential to follow the instructions carefully. Best results can only be obtained by close co-operation on the part of the patient.

The treatment is divided into two stages:

1. Initial adjustment of the dose of Uralyt®-U to a level which brings the pH of the urine into the desired range.

2. Long term administration of Uralyt®-U, with regular checks by the patient.

The granules should be dissolved by stirring in half a glass of water or fruit juice and taken, preferably, after meals. Unused solution must be discarded.

The dosage of Uralyt®-U is adjusted in accordance with the pH value of the urine. This is done as follows:
1. Measure the pH of the urine with the indicator paper.
2. Enter the pH value (colour number) on the enclosed test chart.
3. Take the corresponding dose (number of measuring spoonfuls of Uralyt®-U) and enter it on the chart.

Check the pH value of the urine before each dose of Uralyt®-U.

This pH value (5,6; 5,9; 6,2;6,5; 6,8; 7,0; 7,2; 7,4; 7,7; 8,0) shows the response from the previous dose of Uralyt®-U.

The morning test shows the response from the previous evening dose, the midday test shows the response from the morning dose, etc.

Posology:
How to take Uralyt®-U:
The enclosed measuring spoon holds approximately 2,5 g of the granules.

For most patients it has proved satisfactory to take an average daily dose of 4 measures of the granules (10 g Uralyt®-U) spread uniformly throughout the day in accordance with the following schedule:

Time	Number of spoonfuls
MORNING as early as possible (7-8 a.m.)	1
MIDDAY 2-3 p.m.	1
EVENING as late as possible (about 10 p.m.)	2

This is the standard dosage to stabilise the urine pH within the desired **range (6,2 to 6,8)** and is the range required for treatment of **Uric Acid Calculi**.

During treatment with **uricosuric agents** the pH and is stabilised between **6,2 and 6,8**.

During **cytostatic therapy** the urine pH should be at least **7,0**.

The dose should be individually adjusted in accordance with the pH recorded. It should, however, be noted that any necessary correction of the dose is done on the following day.

Examples:
If at midday the pH value is found to be too high (7,0 or more) there is no point in immediately cutting down the next dose. A test result of "7,0 or more" at midday means that the morning dose was too high. The right course is to reduce the next morning dose so that the pH response at next midday will then fall within the correct range. The same applies to other recordings.

If the morning pH is found to be too low (e.g. 5,9), this means that too small a dose of the granules was taken on the previous evening. Therefore, the next evening dose should be increased.

When changing the dose, it is advisable to increase or decrease it in steps of half a spoonful only.

How to use the indicator paper and test chart:
The pH of fluid is a measure of its acidity or alkalinity. For example, pH 7,0 means that the fluid is neither acid nor alkaline – in other words, neutral. pH readings above 7,0 mean that the reaction is increasingly alkaline, while pH values below 7,0 mean increasing acidity. pH values are measured directly by colour changes on the prepared paper strips (indicatory papers).

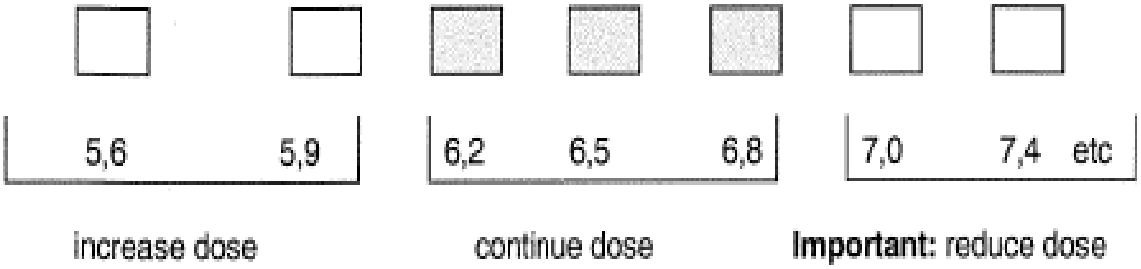
The special indicator paper (enclosed) consists of 52 perforated yellow paper strips and a colour scale with pH number. Every morning, at midday and in the evening, before taking Uralyt®-U, tear off one paper strip and dip it into the fresh urine for a few seconds.

Alternatively, it may be held in the urine stream.

Match the change in colour of the strip at once with the colour scale and mark the corresponding colour number by placing a cross in the appropriate space on the test chart (morning, midday, evening).

Then enter the dose of the granules by writing the number of measuring spoonsful in the space directly after the time.

When the dose has been correctly adjusted, the test which is carried out three times a day before each dose, will give colour numbers of 6,2; 6,5 or 6,8



If the colour number is over 7,0 reduce the dose, except during cytostatic therapy, when the urine pH should be at least 7,0.

Conversely, underdosage is indicated by colour numbers less than 6,2 (5,6 or 5,9). In this case the dosage must be increased.

If the colour number is 6,2 it may be assumed that the dose is correct. The aim should always be to keep within the 6,5 to 6,8 range; 7,0 is to be considered the upper limit.

Method of administration

For oral use.

4.3 Contraindications

Contraindicated in:

- cardiac failure,
- impairment of liver and renal function (in cases of acute or chronic renal failure),
- hypernatremia,
- hyperkalemia,
- metabolic alkalosis *(see section 4.4)*,

- adynamia episodica hereditarian,
- chronic urinary tract infections with urea-splitting bacteria (danger of generation of struvit (magnesium ammonium phosphate) stones),
- low sodium diet,
- case of increased sensitivity to the ingredients of Uralyt®-U,
- concomitant use with potassium-sparing diuretics.

4.4 Special warnings and precautions for use

- Simultaneous administration of citrate and aluminium containing antacids in patients with compromised renal function can result in absorption of dangerously high amounts of aluminium.
- Before taking the first dose the serum electrolytes should be determined and renal function should be monitored.
- Furthermore, the acid base status should be checked when renal tubular acidosis (RTA) is suspected.
- Patients with congestive cardiac failure should not use this product.
- Administer with care in cases of adrenal insufficiency.
- The average daily dose of Uralyt®-U (10 g granules) contains approximately 1,7 g of potassium.
- Before starting therapy all circumstances/malconditions that may be in favour of urinary stones should be excluded. The same is true if there exists a specific therapy (adenoma of parathyroid glands, malignoma with generation of uric acid stones etc.).
- When dissolving uric acid stones, urine pH values of 7,0 and over must be avoided to prevent the formation of a phosphate layer over the existing stone.
- Patients with urinary tract infections should continue antibacterial therapy during treatment with Uralyt®-U *(also see section 4.5).*
- This medicine contains the colouring agent yellow orange S (E110) which may induce allergic reactions including asthma in a sensitive person. Allergy is more often seen in people reacting to 2-acetoxybenzoic acid (acetylsalicylic acid).

4.5 Interaction with other medicines and other forms of Interaction

- Quinolones: Uralyt®-U may reduce the solubility of ciprofloxacin, norfloxacin and ofloxacin in the urine. Patients should be monitored for signs of crystalluria and nephrotoxicity.
- Salicylates: The efficacy of salicylates, when given concurrently with Uralyt®-U, may be decreased due to the alkalisation of the urine and increased urinary excretion.

- Urinary antiseptics: The efficacy of urinary antiseptics which require an acid urine, such as methenamine mandelate and methenamine Hippurate, may be lowered when used concurrently with Uralyt®-U.
- Antacids: Systemic alkalosis may occur when antacids are used concurrently with Uralyt®-U *(see section 4.4)*.
- 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 medicines and peripheral analgesics diminish renal potassium excretion.
- Medicines containing citrate given at the same time as medicines containing aluminium can cause an increase in aluminium absorption. If such medicines must be taken, an interval of at least 2 hours must be allowed between taking each kind of medicine.

4.6 Fertility, pregnancy and lactation

To be used with caution.

4.7 Effects on ability to drive and use machines

Uralyt®-U has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

- Gastro-intestinal complaints may occur.
- Yellow orange S (E110) which may cause allergic reactions.

b. Tabulated list of adverse reactions

Body System	**Undesirable effect**		
	Frequent	Less frequent	Frequency not known
Gastrointestinal disorders:	Mild gastric or abdominal pain	Mild diarrhoea and nausea	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Symptoms:

- Overdose can lead to Hyperkalemia (potassium-plasma level >5 mmol/l), especially 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 parameters, even after taking doses higher than those recommended, since the excretion of any base excess by the kidney provides a natural regulatory mechanism which ensures maintenance of acid-base balance.
- Any rise above the recommended urine pH-range should in no circumstances be allowed to persist for more than a few days, since at considerably high pH levels there is an increased risk of phosphate crystallisation and the long-term establishment of a definite alkalotic metabolic state is in any case undesirable. 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.

Management:

- Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alkali citrates, substances dissolving urinary concrements,
ATC: G04BC01
Uralyt®-U alkalinises the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The other ingredients in Uralyt®-U granules are: Oil of lemon; purified water; Sunset Yellow FCF E110 C.I. No. 15985.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Store in a dry place at room temperature (below 25 ºC).

Keep container tightly closed.

6.5 Nature and contents of container

Screw top container containing 280 g granules.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Viatris South Africa (Pty) Ltd
4 Brewery Street
Isando
Johannesburg
1609

8 REGISTRATION NUMBER(S)

H/18.4/1773

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/05/1995

10 DATE OF REVISION OF TEXT

28 March 2024