Uralyt®-U

SCHEDULING STATUS

SO

PROPRIETARY NAME AND DOSAGE FORM

Uralyt®-U (Granules)

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
11 mEq sodium
27 mEq citrate

Sugar-free

PHARMACOLOGICAL CLASSIFICATION

A. 18.4 Urolitholytics

PHARMACOLOGICAL ACTION

Uralyt®-U alkalinises the urine.

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.

CONTRAINDICATIONS

Contraindicated in cardiac failure, impairment of liver and renal function, hypernatremia, hyperkalemia and alkalosis.
(See **SIDE EFFECTS AND SPECIAL PRECAUTIONS**)

Not to be used concomitantly with potassium sparing diuretics.

WARNINGS

Simultaneous administration of citrate and aluminium containing antacids in patients with compromised renal function can result in absorption of dangerously high amounts of aluminium.

Patients with congestive cardiac failure should not use this product except under the supervision of a doctor. (See **SIDE**

EFFECTS AND SPECIAL PRECAUTIONS)

INTERACTIONS

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 **WARNINGS**)

PREGNANCY AND LACTATION

To be used with caution

DOSAGE AND DIRECTIONS FOR USE

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.

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 should be stabilized 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.

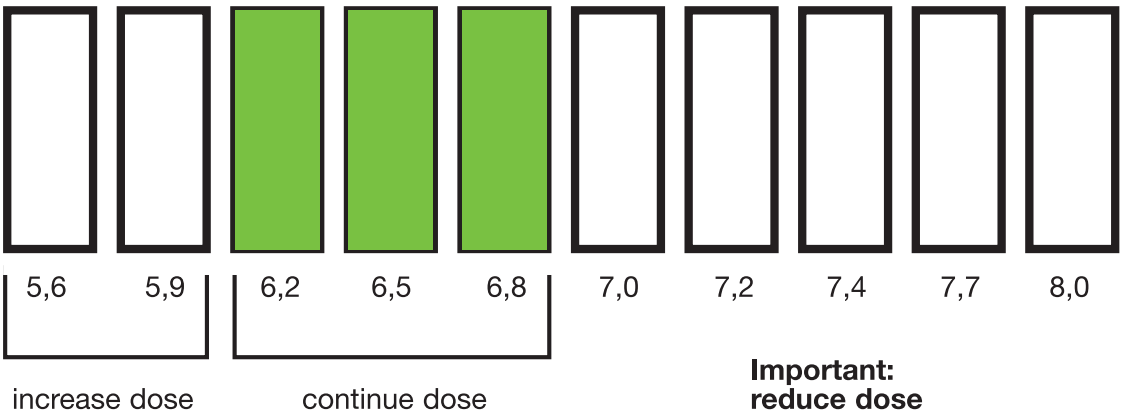
Examples:
If at midday the pH value is found to be too high (7,0 or more) there is no point in immediately cutting down the next dose. A test result of „7,0 or more“ at midday means that the morning dose was too high. The right course is to reduce the next morning dose so that the pH response at next 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 a 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 (indicator papers). The special indicator paper (enclosed) consists of 52 x 2 perforated yellow paper strips and a colour scale with pH numbers. Every morning, at midday and in the evening, before taking **Uralyt®-U**, tear off one paper strip and dip it into fresh urine for a few seconds. Alternatively, it may be held in the urine stream. For this purpose the paper strip may be held with the enclosed peg. 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 spoonfuls 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 6,2 to 6,8 range. 7,0 is to be considered the upper limit.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

In patients with **impaired renal function**, exceeding the recommended dose may lead to metabolic alkalosis.

The 24-hour fluid intake should be at least 2 - 2½ litres. For cardiac patients a lower fluid intake may be necessary.

Administer with care in patients with **cardiac failure** receiving digitalis and in cases of **adrenal insufficiency**. The average daily dose of **Uralyt®-U** (10 g granules) contains approximately 1,7 g of potassium.

Where a **low sodium diet** has been prescribed, it should be noted that 10 g of the granules also contains approximately 1 g of sodium.

Patients with **urinary tract infections** should continue antibacterial therapy during treatment with **Uralyt®-U**. (Also see **INTERACTIONS**)

Gastrointestinal complaints may occur.

When dissolving uric acid stones, urine pH values of 7,0 and over must be avoided in order to prevent the formation of a phosphate layer over the existing stone.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See **SIDE EFFECTS AND SPECIAL PRECAUTIONS**.

Treatment is symptomatic and supportive.

IDENTIFICATION

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

PRESENTATION

Screw top container, containing 280 g granules

STORAGE INSTRUCTIONS

Store in a dry place at or below 25 °C. Keep container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
H/18.4/1773

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
XIXIA PHARMACEUTICALS (PTY) LTD
4 Brewery Street, Isando, Kempton Park, 1600
Republic of South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT
16/05/1995

Namibia Reg.No.: 05/18.4/0399

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TEST Chart

Uralyt®-U

Name

Address

Covering the period from ..... to 20	Chart No:	

Please complete this chart as directed by the doctor and bring it with you when you come for your examination.

Uralyt-U must be taken in strict accordance with the enclosed directions. Please take care to always check the colour number before taking the next dose.

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1	Dose		Please mark appropriate (pH)									
Date	Time	Number of measuring spoonfuls	5,6	5,9	6,2	6,5	6,8	7,0	7,2	7,4	7,7	8,0
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Date	Time	Number of measuring spoonfuls	5,6	5,9	6,2	6,5	6,8	7,0	7,2	7,4	7,7	8,0
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Date	Time	Number of measuring spoonfuls	5,6	5,9	6,2	6,5	6,8	7,0	7,2	7,4	7,7	8,0
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Date	Time	Number of measuring spoonfuls	5,6	5,9	6,2	6,5	6,8	7,0	7,2	7,4	7,7	8,0
	morning											
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Toetskaart

Uralyt®-U

NAAM

ADRES

Dek die tydperk van ..... tot 20	Kaartnr.	

Vul asb. die kaart in soos deur u geneesheer verduidelik en bring dit saam wanneer u vir u ondersoek kom.

Uralyt-U moet streng volgens die ingeslote aanwysings geneem word. Gaan asseblief elke keer die kleurnommer sorgvuldig na voordat u die volgende dosis neem.

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Datum	Tyd	Aantal maatlepels	5,6	5,9	6,2	6,5	6,8	7,0	7,2	7,4	7,7	8,0
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