SCHEDULING STATUS

S0

Uralyt®-U (granules)

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

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

Sugar free

Read all of this leaflet carefully because it contains important information for you

- Uralyt®-U is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Uralyt®-U carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share Uralyt®-U with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What Uralyt®-U is and what it is used for

What Uralyt®-U is:

substances dissolving urinary aggregates.

What Uralyt®-u is used for:

Uralyt®-U alkalinises the urine and it is used to:

- dissolve uric acid calculi in the urinary tract and to prevent further stone formation.
- make the urine more alkaline during treatment with medicines that increase the amount of uric acid excreted in the urine and also during treatment with medicines used to treat various types of cancer.

2. What you need to know before you take/use Uralyt®-U

Do not take/use Uralyt®-U:

- If you are hypersensitive (allergic) to the active/s or any of the other ingredients of Uralyt®-U.
- If you suffer from heart failure.
- If you have liver or kidney disease, or kidneys that do not function properly.
- If you have an increased amount of sodium or potassium in the blood.
- If you have a high alkalinity of your body fluid and tissues.
- If you have an inherited disease characterised by episodic attacks of generalised weakness (adynamia episodica hereditaria).
- If you have kidney stones resulting from bladder infections.
- If you have poor liver function.
- If you are following a low sodium diet.
- If you have increased sensitivity against ingredients of Uralyt®-U.
- If you are using potassium-sparing diuretics (e.g. Aldactone).

Warnings and precautions

Take special care with Uralyt®-U:

Please consult your doctor, pharmacist or other healthcare professional for advice:

- If you are taking antacids which contains citrate or aluminium.
- If you have poor functioning adrenalin glands.
- If you have uric acid stones.
- If you have bladder infections.
- If you are allergic to the colouring agent (yellow orange S (E110)) contained in Uralyt®-U.

Taking other medicines with Uralyt®-U:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Antacids (to neutralise stomach acidity to relieve heartburn).
- Quinolones (antibiotics such as ciprofloxacin, norfloxacin and ofloxacin).
- Salicylates (aspirin).
- Potassium-sparing diuretics (medicines used to increase the amount of fluid passed through urine without too much potassium loss).
- Urinary antiseptics (medicines used to treat bladder infections).
- Medicines to treat heart failure or heart conditions.
- Anti-inflammatory medicines (medicines to treat inflammation in the body).
- Medicines containing citrate and aluminium (as these medicines can cause an increase in aluminium absorption).

Pregnancy and breastfeeding and fertility:

Uralyt®-U should be used with caution during pregnancy and whilst breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking Uralyt®-U.

Driving and using machinery

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

3. How to take/use Uralyt®-U

Do not share medicines prescribed for you with any other person.

Always take/use Uralyt®-U exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The dosage as determined by your healthcare professional should not be changed. Please adhere to the directions for use, otherwise Uralyt®-U will not function optimally.

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

The usual dose is:

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 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 yourself.

Measure the pH of the urine with the indicator paper.

Enter the pH value (colour number) on the enclosed test chart.

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 much and how often should you 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
as early as possible (7-8 a.m.)	1
2-3 p.m.	1
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 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 occurs 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 (indicator papers).

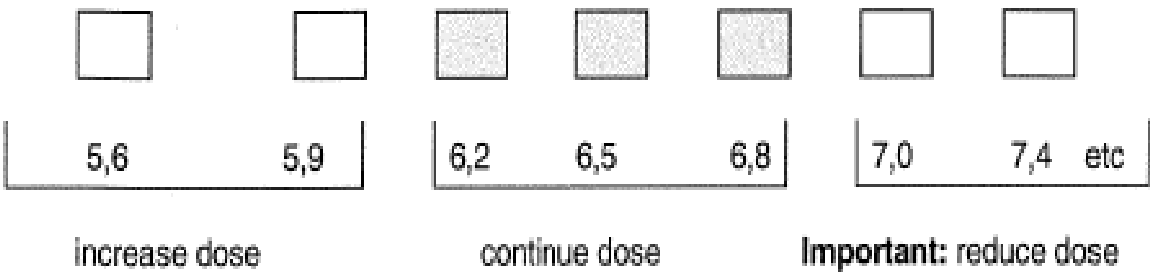
The special indicator paper (enclosed) consists of 52 perforated yellow paper strips and a colour scale with pH numbers. Every morning, at midday and in the evening, before taking Uralyt®-U, tear off one paper strip and dip it into fresh urine for a few seconds.

Alternatively, it may be held in the urine stream.

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.

If you take more Uralyt®-U than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms:

- High potassium levels in the body.
- Increased pH levels of the body.

Management:

- Treatment is symptomatic and supportive.

If you forget to take/missed a dose of Uralyt®-U

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Uralyt®-U can have side effects.

In patients with impaired renal function, exceeding the recommended dose may lead to a condition called metabolic alkalosis. The 24-hour fluid intake should be at least 2 to 2½ litres. For heart patients, a lower fluid intake may be necessary.

Not all side effects reported for Uralyt®-U are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Uralyt®-U, please consult your healthcare professional for advice.

If any of the following happens, stop taking Uralyt®-U and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Uralyt®-U. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Mild gastric or stomach pain.

The following side effects have been reported less frequently:

- Mild diarrhoea (loose stools) and nausea (feeling sick).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

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

By reporting side effects, you can help provide more information on the safety of Uralyt®-U.

5. How to store Uralyt®-U

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep container tightly closed.
- Do not use this medicine after the expiry date printed on the container.
- Do not share medicines prescribed for you with others.
- Store in the original package/container.
- Do not store in a bathroom.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Uralyt®-U contains:

The active substance is: 2,43 g potassium sodium hydrogen citrate (6:6:3:5)

Equivalent to: 11 mEq potassium, 11mEq sodium, 27 mEq citrate.

The other ingredients are: Oil of lemon; purified water; Sunset Yellow FCF E110 C.I. No. 15985.

What Uralyt®-U looks like and contents of the pack

What Uralyt®-U looks like:

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

Contents of the pack

Screw top container containing 280 g granules.

Holder of Certificate of Registration and Manufacturer

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando

Johannesburg

1609

DATE OF PUBLICATION OF THE PACKAGE INSERT

16/05/1995

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