

URALIME Effervescent Granules

Sodium bicarbonate 1.76 g, Tartaric acid 890 mg, Citric acid 720 mg and Sodium citrate 630 mg Effervescent Granules Sachet

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What is URALIME used for

Indicated for relieving of discomfort in mild urinary tract infection; symptomatic relief of dysuria; to enhance the action of certain antibiotics especially some sulphonamides; in gout as urinary alkalinizers to prevent crystallisation of urates and dissolution of uric acid stones.

How URALIME works

Pharmacology class: Urinary and gastric alkalinizer.

Sodium bicarbonate acts as urinary alkalinizer by increasing the excretion of free bicarbonate ions in the urine, thus effectively raising the urinary pH.

Sodium citrate is metabolized to bicarbonates, which increases urinary pH by increasing the excretion of free bicarbonate ions, without producing systemic alkalosis when administered in recommended doses.

Sodium citrate is used to make the urine alkaline in the treatment of urinary tract infections.

Citric acid increases the secretion of urine and renders it less acidic. It is also used in the preparation of effervescent granules to aid effervescence.

Before you use URALIME

-When you must not use it

Do not give this medicine to children under 12 years of age unless advised to do so by a doctor.

Patients should be advised to consult your doctor or pharmacist before using this medicine if you are taking other medicines or if you have kidney problems, heart problems or high blood pressure.

-Before you start to use it

Do not give this medicine to children under 12 years of age unless advised to do so by a doctor.

Patients should be advised to consult your doctor or pharmacist before using this medicine if you are taking other medicines or if you have kidney problems, heart problems or high blood pressure.

Patients should be advised to consult a doctor if pain or irritation persists for more than 48 hours of if you notice blood in your urine.

This preparation contains 650 mg of sodium per sachet and should be taken into account if on a low sodium diet. Also contains soya bean products and sugars.

The clinical condition of the patient should be evaluated and laboratory determinations (e.g., serum electrolytes, acid-base balance) obtained periodically during URALIME therapy, particularly in patients with renal disease.

-Taking other medications

General: Alkalinization of the urine due to the use of URALIME, theoretically may result in a decreased therapeutic effect of the following medications: chlorpropamide, lithium, salicylates and tetracyclines.

Alternatively, alkalinization of the urine due to the use of URALIME, theoretically may result in an increased therapeutic effect of the

following medications: amphetamines, ephedrine/pseudoephedrine.

Antacids:

Concomitant use of URALIME with an antacid by patients with compromised renal function may result in the absorption of dangerously high amounts of aluminium.

Co-administration of antacids with citrates, such as contained in URALIME, may result in systemic alkalosis, while concurrent administration of antacids with sodium citrate and sodium bicarbonate may lead to the development of calcium stones in patients with uric acid stones. It may also cause hypernatremia.

Quinolones:

The sodium citrate in URALIME may reduce the solubility of quinolone antibiotics, such as ciprofloxacin, norfloxacin, or ofloxacin in the urine. Patients should therefore be monitored for signs of crystalluria and nephrotoxicity.

Salicylates:

Co-administration of salicylates with the sodium citrate in URALIME may increase urinary excretion and reduce therapeutic effects of salicylates as a result of urinary alkalinization.

Tetracyclines:

Due to an increase in intragastric pH, the absorption of tetracyclines may be decreased when it is co-administered with URALIME should therefore not be taken within 1 to 2 hours of tetracycline administration.

Ketoconazole:

Since the sodium bicarbonate in URALIME may increase gastrointestinal pH, the absorption of ketoconazole may be markedly reduced with concurrent administration. Patients should wait at least 2 hours before taking

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URALIME following ketoconazole administration.

Methenamine:

URALIME should not be administered with urinary tract antiseptics which require acidic urine, such as methenamine mandelate and methenamine hippurate.

Laxatives:

Concurrent administration of citrates with laxatives may have an additive effect.

How to use URALIME

-How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: Dissolve the contents of 1-2 sachets in a glass of cold water. It may be taken 4 times daily for 5 days unless advised to do so by the physician.

Children (under 12 years of age): Do not give unless advised to do so by physician.

-When to use it

Indicated for relieving of discomfort in mild urinary tract infection; symptomatic relief of dysuria; to enhance the action of certain antibiotics especially some sulphonamides; in gout as urinary alkalinizers to prevent crystallisation of urates and dissolution of uric acid stones.

-How long to use it

Do not stop your treatment just because you feel better. It is important that you carry on taking URALIME for as long as your doctor has told you to.

It may be taken 4 times daily for 5 days unless advised to do so by the physician.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-If you forget to use it

If you missed a dose, take the next dose as per your schedule of dosing as it may be taken maximum of 4 times a day.

-If you use too much (overdose)

Treatment is symptomatic and supportive and consists mainly of correction of fluid and electrolyte balance. Consult a doctor in known cases of overdosage.

While you are using it

-Things you must do

Try to take URALIME as per your schedule of each day. Dissolve the contents of 1-2 sachets in a glass of cold water. It may be taken 4 times daily for 5 days unless advised to do so by the physician.

Even if you feel better, do not alter or discontinue the daily dose of URALIME without first consulting your doctor.

-Things you must not do

Children and adolescents: Do not give this medicine to children under 12 years of age unless advised to do so by a doctor.

Pregnancy, breast-feeding and fertility: If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy: Studies regarding the effect of citrates on pregnancy have not been done.

Nursing mothers: Caution should be exercised when administered to a nursing mother. If you are taking URALIME, your doctor will discuss with you whether you should breast-feed considering the benefit to you of your therapy and the benefit to your baby of breast-feeding. You should

not do both. Talk to your doctor about the best way to feed your baby if you are taking this medicine.

-Things to be careful of

Driving and using machines: URALIME has negligible influence on the ability to drive and use machines.

Side effects

The tartarate component of Sodium bicarbonate, Tartaric acid, Citric acid and Sodium citrate Effervescent Granules Sachet may be incompletely absorbed. Because of this, Sodium bicarbonate, Tartaric acid, Citric acid and Sodium citrate Effervescent Granules Sachet may exert a mild laxative effect. Prolonged and excessive use may cause systemic alkalosis and/or hyponatremia.

Sodium bicarbonate may cause flatulence. Mild diuresis may occur.

Tell your doctor if you experience any of these behaviours; he/she will discuss ways of managing or reducing the symptoms.

If any other side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of URALIME

-Storage

Store below 30°C. Store in the original package in order to protect from moisture.

After dissolving the sachet as recommended for dosing, it is to be used whole at a time and do not store for later use.

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-Disposal

No special disposal required.

Product Description

-What it looks like

Granules: white to off-white coloured, lemon flavoured granules.

Reconstituted solution: The reconstituted solution is clear, and lemon flavoured.

-Ingredients

- Active ingredient(s)

Sodium bicarbonate,
Tartaric acid, Citric acid
anhydrous and Sodium
citrate anhydrous.

- Inactive ingredient(s)

Lemon Flavour
501282TDI11091

-MAL number

MAL24116010XC

Manufacturer

Ind-Swift Laboratories Limited
Off- NH-21, Village Jawaharpur,
Tehsil Derabassi, Distt. S.A.S Nagar
(Mohali) Punjab (India) Pin -140507

Product Registration Holder

Synerrv Sdn. Bhd.
SO-29-2, Menara 1,
KL Eco City, Jalan Bangsar,
Kg. Haji Abdullah Hukum,
59200 Kuala Lumpur, Malaysia

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