

URISOL

(Sodium Bicarbonate 1.76g, Tartaric Acid 890mg, Citric Acid 720mg and Sodium Citrate 630mg Effervescent Granules Sachet)

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What is Urisol 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 alkalinisers to prevent crystallisation of urates and dissolution of uric acid stones.

How Urisol works

Pharmacology Class: Urinary and Gastric Alkalinizer

Sodium bicarbonate acts as urinary alkaliser 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 Urisol

-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 pressures.

-Before you start to use it

Special warnings and precautions

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 pressures.

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

This preparation contains 650mg 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 (eg. serum electrolytes, acid-base balance) obtained periodically during Urisol therapy, particularly in patients with renal disease.

-Taking other medications

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

Alternatively, alkalinisation of the urine due to the use of Urisol, theoretically, may result in an increased therapeutic effect of the following medications: amphetamines, ephedrine/ pseudoephedrine.

Antacids:

Concomitant use of Urisol 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 Urisol, 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 hypernatraemia.

Quinolones:

The sodium citrate in Urisol 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 Urisol may increase urinary excretion and reduce therapeutic effects of salicylates as a result of urinary alkalinisation.

Tetracyclines:

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

Ketoconazole:

Since the sodium bicarbonate in Urisol may increase gastrointestinal pH, the absorption of ketoconazole may be markedly reduced with concurrent administration. Patients

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should wait at least 2 hours before taking Urisol following ketoconazole administration.

Methenamine:

Urisol 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 Urisol

-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: Children under 12 years old

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 alkalinisers 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 Urisol 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 miss 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 Urisol 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 Urisol 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 Urisol, 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

Urisol has negligible influence on the ability to drive and use machines.

Side effects

The tartrate 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 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 of the 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 reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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Storage and Disposal of Urisol

-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.

-Disposal

No special disposal is required.

Product Description

-What it looks like

Effervescent granules in a sachet. White to off white colored, lemon flavoured granules.

Reconstituted Solution: The reconstituted solution is clear and lemon flavored.

-Ingredients

- Active ingredient(s)
Sodium Bicarbonate,
Tartaric Acid, Citric Acid
Anhydrous and Sodium
Citrate Anhydrous
- Inactive ingredient(s)
Lemon Flavor
501282TDI1091

-MAL number

MAL22046033X

Manufacturer

Ind-Swift Limited
Off. NH-21, Village
Jawaharpur, Tehsil
Derabassi, District SAS Nagar
(Mohali) Punjab -140507, India

Product Registration Holder

HEALOL PHARMACEUTICALS
SDN BHD
74-3, Jalan Wangsa Delima 6, KLSC
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Malaysia

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