URON

Sodium Bicarbonate, Tartaric acid, Citric acid and Sodium Citrate Effervescent Granules Sachet

COMPOSITION:

Each 4g sachet contains:

Sodium Bicarbonate BP	1.76g
Tartaric Acid BP	890mg
Citric Acid Anhydrous BP	720mg
Sodium Citrate Anhydrous USP	630mg

DESCRIPTION:

Appearance of powder: White to off white coloured, lemon flavoured granules.
Appearance of solution: Reconstituted solution is clear and lemon flavoured.

PHARMACOLOGY:

Sodium bicarbonate acts as a systemic and urinary alkaliniser by increasing the excretion of free bicarbonate ions in the urine, thus effectively raising the urinary pH. By maintaining alkaline urine, the actual dissolution of uric acid stones may be accomplished. It is also a valuable adjuvant when administered with uricosuric agents in gout therapy, since urates tend to crystallise out of acidic urine.

Sodium Citrate and Citric Acid:
A rise in urinary pH increases the solubility of cysteine in the urine and the ionization of uric acids to more soluble urate ion. By maintaining alkaline urine, the actual dissolution of uric acid stones may be accomplished.

Tartaric acid in combination with bicarbonates acts as the acid component of effervescent granules.

PHARMACOKINETICS

Sodium citrate is metabolised to bicarbonates, which increases urinary pH by increasing the excretion of free bicarbonate ions, without producing systemic alkalosis when administered in recommended doses. Sodium bicarbonate is excreted through renal and also via lung by forming CO2. Sodium citrate, citric acid and absorbed tartaric acid are excreted through urine.

INDICATIONS

- For prevention of urates crystallisation in gout therapy.
- For relieving discomfort in mild urinary tract infections.
- For symptomatic relief of dysuria (painful or difficult urination).
- To enhance the action of certain antibiotics, especially sulphonamides.

DOSAGE AND ADMINISTRATION:
4g to 8g (1 to 2 sachets) dissolved in cold water four times daily or as recommended by pharmacist or doctor

Route of Administration
Oral administration

CONTRAINDICATIONS:
Renal failure or hypernatraemia; in conjuction with hexamine mandelate or hexamine hippurate therapy because an acid urine is needed. Caution is advised in overt and accult cardiac failure. Concomitant use of urinary alkalinisers and quinolone antibiotics should be avoided; crystalluria may be more likely to occur in alkaline urine.

PRECAUTIONS/WARNINGS:
Those on a low sodium diet should take into account of the sodium content (650 mg per sachet) of this product.

DRUG INTERACTIONS:
Alkalinisation of the urine due to the use of Sodium Bicarbonate, Tartaric Acid, Citric Acid and Sodium Citrate Effervescent granules, theoretically, may result in a decreased therapeutic effect of the following medications: chlorpropemide, lithium, salicylates and tetracyclines. Alternatively, alkalinisation of the urine due to the use of Sodium Bicarbonate, Tartaric Acid, Citric Acid and Sodium Citrate Effervescent granules, theoretically, may result in an increased therapeutic effect of the following medications: amphetamines and ephedrine/pseudoepherine.

Antacid: Concurrent use of antacids with sodium citrate and sodium bicarbonate may promote The development of calcium stones in patients with uric acid stones and may also cause hypernatremia. Concurrent use of aluminium-containing antacids with salts can increase aluminium absorption, possibly resulting in acute aluminium toxicity, especially in patients with renal insufficiency.

Quinolones: Citrates may reduce the solubility of ciprofloxacin, norfloxacin or ofloxacin in the urine. Patients should be observed for signs of crystalluria and nephrotoxicity.

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

Hexamine hippurate/mandelate (inactive) is hydrolysed to formaldehyde (active) in acidic urine. Urinary alkalinisation prevents the formation of formaldehyde and thus reduces the antibacterial effect of hexamine.

PREGNANCY:
Effects of this product on pregnant women have not been carried out.

NURSING MOTHERS:
Caution should be exercised when administered to a nursing mother.

SIDE EFFECTS/ADVERSE REACTIONS:
The tartrate component of Sodium Bicarbonate, Tartaric Acid, Citric Acid and Sodium Citrate Effervescent granules 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 a systemic alkalosis and/or hypernatremia.

OVERDOSAGE:
Overdosage may result in metabolic alkalosis. Sodium Bicarbonate, Tartaric Acid, Citric Acid and Sodium Citrate Effervescent granules should be discontinued, appropriate treatment instituted and electrolyte and acid-base determinations should be carried out.

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

PACK SIZE:
Effervescent granules, 4g per sachet: 30 sachets per pack.

PRODUCT REGISTRATION HOLDER:
Medispec (M) Sdn Bhd,
B-1-07, Jalan SS 25/22, Taman Mayang, 47301 Petaling Jaya, Selangor, Malaysia

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

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