Disodium Hydrogen Citrate Syrup
CITRALKA®

1. NAME OF MEDICINAL PRODUCT

CITRALKA

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains
Disodium Hydrogen Citrate B.P. 1.53 g.

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

To render the urine alkaline in conditions such as pyelitis, cystitis, urethritis, urolithiasis [1,2,3,4] and during treatment of urinary tract infections with antibiotics whose action is enhanced by an alkaline pH[5,6] such as sulphonamides and fluroquinolones; or to overcome the tendency to acute or chronic metabolic acidosis[7] in acute infections and dehydration.

4.2 Posology and Method of Administration

Adults:	30 ml (two tablespoonfuls) 4 times daily.
Children 6 to 12 years:	10 or 15 ml (two or three teaspoonfuls) 3 to 4 times daily.

To be taken in water or milk. Adults may take it without dilution, followed by liquid, if preferred.

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4.3 Contraindications

Citralka is contraindicated in patients with severe renal impairment and associated oliguria, azotemia or anuria; untreated Addison's disease; acute dehydration; heat cramps; and severe myocardial damage. In addition, sodium salts are contraindicated in patients on sodium restricted diet.

4.4 Special Warnings and Special Precautions for Use

Citralka should be used with caution in patients with edematous sodium retaining states; congestive heart failure; hypertension; pulmonary or peripheral edema or toxemia of pregnancy. Serum electrolytes, particularly serum bicarbonate levels, should be monitored in patients with renal disease. Caution is advised in patients with low urinary output or reduced glomerular filtration rates. Precaution is also advised while using blood products containing citrate in patients with acute liver failure.[6,7]

4.5 Interactions with Other Medicaments and Other Forms of Interaction

Concurrent administration of aluminium antacids and citrate salts is not recommended, especially in patients with renal insufficiency. Citrate salts taken orally can enhance absorption of aluminium from the gastrointestinal tract. This may lead to increased serum concentration of aluminium and encephalopathy especially in the elderly. It is recommended that if concurrent use cannot be avoided, patients should be monitored for possible acute aluminium toxicity (e.g., encephalopathy, seizures, coma) and doses should be adjusted accordingly.[7]

Urinary alkalinizers including disodium hydrogen citrate may increase the excretion and decrease the serum levels of chlorpropamide, lithium, methotrexate, methenamine, salicylates and tetracyclines. This may lead to a decrease in the pharmacologic effects of these drugs upon concomitant administration.[7]

Urinary alkalinizers have also been reported to decrease the excretion and increase the serum levels of drugs such as mecamylamine, flecainide, quinidine and sympathomimetics, possibly increasing their pharmacologic effects.[7]

4.6 Pregnancy and Lactation

Safety of Citralka for use in human pregnancy and lactation has not been established. Use in pregnancy or in nursing mothers should be considered only when the possible benefits outweigh the potential risks.

4.7 Effects on Ability to Drive and Use Machines

No special precautions required.

4.8 Undesirable Effects

Excessive administration of bicarbonate or bicarbonate forming compounds may lead to the following:[6,7]

Hypocalcemia: In patients with acute hepatic failure, impaired citrate utilization and clearance can result in hypocalcemia.

Hypokalemia and metabolic alkalosis especially in patients with impaired renal function, especially in the presence of hypocalcemia or when excessive doses are given. Symptoms include mood changes, tiredness, shortness of breath, muscle weakness, and irregular heartbeat.

Excessive doses of sodium salts may also lead to sodium overload and hyperosmolarity.

Large doses of oral citrate salts may result in gastrointestinal events such as diarrhoea, nausea and vomiting, and a laxative effect. Diluting with large amounts of water and administration after meals can minimize these effects.

4.9 Overdose

Overdosage with sodium salts may cause serious electrolyte disturbances. Ingestion of large amounts of disodium hydrogen citrate irritates the gastrointestinal mucosa, and may result in diarrhoea, nausea, vomiting, hypernoia (excessive mental activity), edema and convulsions. Treatment includes usual supportive measures such as providing an adequate airway and ventilation and maintaining vascular volume and tissue perfusion. Magnesium sulphate may be given as a cathartic.[8]

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Disodium hydrogen citrate, also known as sodium acid citrate, is a urinary alkalinizer. It renders the urine less acidic and promotes a mild diuresis.

5.2 Pharmacokinetic Properties

Disodium hydrogen citrate is metabolized after absorption to sodium bicarbonate. Oxidation is virtually complete, less than 5% of citrate is excreted unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose IP, Liquid Glucose NF, Sodium benzoate IP, Saccharin sodium IP, Tartrazine, Orange flower flavour, Talcum*, Purified water.

* Talcum is filtered out during the filtration operation and does not form part of formulation.

6.2 Incompatibilities

Not known.

6.3 Shelf Life

24 months.

6.4 Special Precautions for Storage

Store protected from light and excessive heat

6.5 Nature and Contents of Container

Amber coloured PET Bottles of 100 ml & 200 ml

6.6 Instructions for Use and Handling

No special instructions.

References:

1. Shekarriz B, Stoller ML. Uric acid nephrolithiasis: current concepts and controversies. *J Urol.* 2002 Oct; 168:1307-14.
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3. Liebman SE, Taylor JG, Bushinsky DA. Uric acid Nephrolithiasis. *Curr Rheumatol Rep*. 2007 Jun;9(3):251-7.
4. C. Türk (chair) et al. Guidelines on Urolithiasis. March; European Association Urology 2013
5. J. Aagaard, P. O. Madsen, P. Rhodes and T. Gasser. MICs of cipro-floxacin and trimethoprim for *Escherichia coli*: influence of pH, inoculum size and various body fluids. Infection. 1991; 19(3):S167–S169.
6. Marika Kamberi et al. Influences of Urinary pH on Ciprofloxacin Pharmacokinetics in Humans and Antimicrobial Activity In Vitro versus Those of Sparfloxacin. Antimicrob Agents Chemother. 1999 March;43(3): 525–529.

7. Sweetman SC (ed). M*artindale The Extra Pharmacopoeia*, 33rd edition, 2002, London: Royal Pharmaceutical Society: 1186-87.

8. Kastrup E K (ed). *Drug Facts and Comparisons*, 57th ed., 2003, St Loius A Walters Kluwer Company: 58-59.