SUMMARY PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT:

URISTAR SYRUP (Disodium Hydrogen Citrate 1.53 gm/5ml Syrup)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

COMPOSITION:
Label claim:
Each 5.0ml Contains
Disodium Hydrogen Citrate 1.53 gm Syrup.
Excipients ……..…. q.s.
Flavored syrup base.

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 pH5,6 such as sulphonamides and fluroquinolones; or to overcome the tendency to acute or chronic metabolic acidosis7 in acute infections and dehydration

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Route of administration- Oral

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.

4.3 CONTRAINDICATIONS

Uristar Syrup 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 PRECAUTIONS FOR USE

For the use of URISTAR SYRUP (Disodium Hydrogen Citrate Syrup 1.53mg/5ml Syrup) following precautions & warnings should take:

Uristar Syrup 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 INTERACTION WITH OTHER MEDICINAL PRODUCTS 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 Uristar Syrup 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 THE ABILITY TO DRIVE AND USE MACHINES

No special precautions require

4.8 OVER DOSAGE

In the event of significant overdose, serum electrolytes should be evaluated as soon as possible, appropriate steps taken to correct an abnormalities and levels monitored until return to normal levels is established. This is particularly important in the very young and in cases of severe hepatic of renal failure.

5. PHARMACOLOGICAL PARTICULARS

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

No.	Name of the Excipients	Specification	Function
1	Disodium Hydrogen Citrate	BP	
2	Sorbitol solution 70 %	BP	Sweetener
3	Sodium methyl paraben	BP	Preservative
4	Sodium propyl paraben	BP	Preservative
5	Sodium Benzoate	BP	Preservative
6	Sodium Saccharine	BP	Sweetner

7	Col. Tartrazine Supra	IH	Colour
8	Ess. Orange Liquid	IH	Preventing dehydration

6.2. INCOMPATIBILITIES

Not Sated

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. SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No Special instructions

7. DATE OF REVISION OF TEXT

01/11/2021