Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

URIFLOW LIQUID (Disodium Hydrogen Citrate 1530 mg/5ml)

2. Qualitative and quantitative composition

Each 5ml contains:

Disodium Hydrogen Citrate BP

1.53gm Flavoured Syrupy Base Q.S.

Colour: Tartrazine WS
"For a full list of excipients, see section 6.1."

3. Pharmaceutical form

Oral Solution

Yellow coloured syrupy liquid filled in amber round pet bottle.

4. Clinical particulars

4.1 Therapeutic indications

Disodium Hydrogen Citrate is a urinary alkalizer that is primarily used to restore the normal pH of urine. A few conditions which can be treated and prevented by the use of Disodium Hydrogen Citrate are:

- Urinary Acidosis
- Urinary Tract Infection
- Kidney stones
- Burning Micturition

4.2 Posology and method of administration

The patient should administer Disodium Hydrogen Citrate in accordance with the instructions advised by the doctor. Doctors usually prescribe the medicine in following doses:

Adult: 15-30 mL bid-tid.
Child: <7 yr 2 mL tid; 7-12 yr 5 mL tid.
However, the dosage may vary with the severity of the ailment to be treated. BMI of the patient, age of patients and other underlying health concerns are a few factors that may help decide the dosage.
Missed Dosage: The patient should take the missed dose as soon as it is remembered. However, it is advisable not to take the missed dose if it is almost time for the next dose.
Over Dosage: Overdosage may show serious side effects or drug toxicity and thus one should refrain from taking an overdose. However, if overdosage is suspected, one must rush to a doctor to seek immediate medical attention.

4.3 Contraindications

- Allergy to the drug.
- High blood pressure (Since it contains Sodium)
- Fluid accumulation in the body (Oedema)
- Metabolic derangements like high osmolality or increased alkalinity of the blood, low blood calcium levels
- Kidney Dysfunction

4.4 Special warnings and precautions for use

- Hypocalcaemia, hypoventilatory states, alkalosis. Renal disease. Children including neonates. Pregnancy and lactation.
- The medicine should be taken orally, preferably with food or immediately after food to avoid gastric disorders.

4.5 Interaction with other medicinal products and other forms of interaction

- Warfarin (Serious)
- Phenindione (Serious)
- Theophylline (Minor)
- Acenocoumarol (Nicoumalone) (Serious)
- Corticosteroids
- Barbiturates
- Ephedrine
- Amphetamines
- Methotrexate
- Salicylates
- Quinidine
- Tetracycline
- Pseudoephedrine
- Potassium depleting diuretics

4.6 Pregnancy and Lactation

Safety of Disodium Hydrogen Citrate 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

Apart from the intended effects of a drug, they are bound to show some side effects in certain cases. Some of the side effects that may appear with the use of Disodium Hydrogen Citrate are:

- Flatulence
- Nausea
- Vomiting
- Diarrhoea
- Stomach cramps
- Frequent Urination
- Gastrointestinal Ulcers
- Tiredness
- Headache
- Anxiety
- Mood Swings
- Imbalance in potassium levels in the blood

These side effects may or may not be life-threatening, but in case the patient experiences any of the above-mentioned side effects, he or she must rush to a doctor to seek immediate medical attention.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to report any suspected adverse reactions to the National Regulatory Agents.

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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Urinary alkalinizer. **ATC code:** B05CB02

Mechanism of action

Disodium hydrogen citrate is metabolised to bicarbonate, which then

increases urinary pH by increasing the excretion of free bicarbonate ions, thereby increasing the solubility of cystine in the urine and the ionization of uric acid to more soluble urate ion.

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. Onset: <1 min. Duration: 4-6 hr.

5.3 Preclinical safety data

No data available

6. Pharmaceutical Particulars

6.1 List of Excipients

Sucrose(Pharmagr
ade)
Sorbitol 70%
Sodium
Methylparaben
Sodium Propyl
Paraben
Sodium Benzoate
Acesulfame
potassium
Liquid Flavour
Apricot
Colour Tartrazine
Supra
Purified Water.

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

36 Months

6.4 Special Precautions for storage

Store below 30°C. Protect from light and moisture.

6.5 Nature and Content of container

Yellow coloured syrupy liquid filled in amber round pet bottle, 100 ml Bottle packed in printed carton along with insert.

6.6 Special precautions for disposal and other handling

Not Applicable

7. Marketing Authorization Holder

Marketing Authorization Holder:
Dolopharma Healthcare Limited
P.O. Box 102976-00101, Nairobi, Kenya
Manufacturing Site Address:
Bueno Salud Care (India) Pvt. Ltd.
Plot No.: K-20 & K-21, Gallops Industrial Park-2, Bavla-Rajkot N.H.No:8, Village: Vasana Chacharawadi, Tal: Sanand, Dist: Ahmedabad-382 213, Gujarat, India

8. Marketing Authorization Number

9. Date of first authorization/renewal of the authorization

05/06/2014

10. Date of revision of the text

May 2026