Summary of Product Characteristics	
CITAL **(Disodium Hydrogen Citrate Liquid)**	

1. NAME OF THE MEDICINAL PRODUCT

CITAL (Disodium Hydrogen Citrate)

Strength:

Each 5 ml contains
Disodium Hydrogen Citrate BP .....1.37 gm
Colours: Tartrazine, Carmoisine, Sunset Yellow FCF
Flavoured Syrupy Base .....q.s.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains
Disodium Hydrogen Citrate BP ..... 1.37 gm
Colours: Tartrazine, Carmoisine, Sunset Yellow FCF
Flavoured Syrupy Base ..... q.s.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated in relieving urinary tract infections, In relieving the burning sensation and dysuria and in acidosis following vomiting, diarrhoea. Also used as an adjuvant to urinary antibiotics i.e. Ampicillin, Gentamicin and also given along with Sulpha drugs or Cotrimoxazole to prevent crystallisation, In metabolic acidosis and to prevent stone formation in the urinary tract.

4.2 Posology and method of administration

Adults: 15-30 ml twice or thrice daily In 200 ml of water.
Children (7-12 years): 5 ml thrice daily In 150 ml to 200 ml of water.
Infants : 2 ml thrice daily in 150 ml to 200 ml of water.

4.3 Contraindications

Contraindicated in patients with impaired renal function which may lead to sodium overload in the body causing oedema and hypertension.

4.4 Special warnings and precautions for use

Adequate kidney function must be ensured so as to prevent excess Sodium retention in the body.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions have been reported.

4.6 Pregnancy and lactation

Pregnancy - Use with caution

Lactation - May be used

4.7 Effects on ability to drive and use machines

Not Applicable.

4.8 Undesirable effects

Side effects include taste disturbances, nausea, vomiting.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

4.9 Overdose

Symptoms of overdosage include diarrhoea, nausea, vomiting. In case of over dosage symptomatic therapy i.e. gastric lavage, activated charcoal and general supportive measures are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Bioavailability of Cital liquid is 100%.

Citrate undergoes almost complete metabolic breakdown. Only 1.5 to 2% of the original dose appears unchanged in the urine. Ingestion of 10 g potassium sodium hydrogen citrate yields approximately 36 mmol of citrate; this is equivalent to less than 2% of the daily turnover of citrate involved in energy metabolism within the body. After a one-day intake of potassium sodium hydrogen citrate the equivalent amounts of sodium and potassium are quantitatively excreted via the kidneys within 24 -28 hours. During long-term administration, the daily excretion of sodium and potassium is in equilibrium with the daily intake. No significant changes in blood gases or in serum electrolytes have been observed. This indicates that by virtue of renal regulation of alkalinization, the acid base balance of the body remains intact and that, provided renal function is adequate, any possibility of accumulation of sodium or potassium can be excluded. According to the results obtained from investigations in animals, potassium sodiu hydrogen citrate has a very low toxicity. Chronic tests in dogs and rats revealed that oral doses up to 1.2 g/kg or 3 g/kg bodyweight were safe. Toxicological tests on reproduction in rats and rabbits at 2 g/kg bodyweight revealed no teratogenic or embryotoxic/fetotoxic effects.

5.2 Pharmacokinetic properties

Salts of strong bases with weak acids are suitable for alkalinization (neutralisation therapy) and the acid component is assumed to be metabolisable. The citrate ion from alkali citrates undergoes oxidative metabolic breakdown to CO2 or bicarbonate. The base excess resulting from the remaining alkali ions is eliminated via the kidneys and produces an increase in urine pH. Neutralization or alkalinization of the urine can be achieved by oral administration of alkali citrates, the response being dose-dependent. 1 g of potassium sodium hydrogen citrate (8.8 mmol alkali) causes the urine pH to increase by 0.2 – 0.3 units. As a result the dissociation rate increases and hence the solubility of uric acid or cystine does too. Litholysis of uric acid calculi is radiologically

demonstrated. Besides urine alkalinisation citrate excretion is raised as a result of an increased citrate secretion and simultaneous lowering of calcium excretion. These mechanisms lead to a decrease of the activity product of calcium oxalate, because in the weak base citrate forms stable complexes with calcium. Furthermore, the citrate ion must be regarded as a very effective physiological inhibitor of calcium oxalate (and calcium phosphate) crystallisation and aggregation of these crystals. Increased concentrations of uric acid in urine remain soluble; hence a heterogeneous crystallisation of calcium oxalate is avoided. Citrate undergoes almost complete metabolic breakdown. Only 1.5 to 2% of the original dose appears unchanged in the urine. Ingestion of 10 g potassium sodium hydrogen citrate
yields approximately 36 mmol of citrate; this is equivalent to less than 2% of the daily turnover of citrate involved in energy metabolism within the body.
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5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose,
Methyl Hydroxybenzoate,
Propyl Hydroxybenzoate,
Disodium Edetate,
Sodium Hydroxide,
Sodium Benzoate,
Saccharin Sodium,
Colour Tartrazine Yellow (Supra) 1694,
Colour Carmoisine (Supra),
Color Sunset Yellow FCF (Supra) 15985,
Essence Rasberry Sweet (Quest),
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30oC.Protect from light.

6.5 Nature and contents of container

Amber coloured PET bottle of 100 ml.

6.6 Special precautions for disposal <and other handling>

No special requirements

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

MARKETING AUTHORIZATION HOLDER:
Indoco Remedies Limited
Indoco House, 166, C.S.T Road,
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8. MARKETING AUTHORIZATION NUMBER - 12844

9. DATE OF FIRST <REGISTRATION> / RENEWAL OF THE <REGISTRATION>
31st December 2024

10. DATE OF REVISION OF THE TEXT – 22.07.2025