Summary of Product Characteristics (SmPC)

1. Name of the medicinal product
KRISHAT MIST. POTASSIUM CITRATE B.P.C.

2. Qualitative and quantitative composition
Potassium Citrate BP 3gm/10ml.
Citric acid BP 0.5gm/10ml.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Oral Solution

4. Clinical particulars

4.1 Therapeutic indications
For the symptomatic relief of dysuria associated with mild urinary tract infections, especially cystitis. Indications stated on label: For the relief of the symptoms of cystitis and other mild urinary tract infections.

4.2 Posology and method of administration
Oral:
Recommended Doses
Unless directed otherwise by a doctor:
Adults including the elderly, and children over 6 years: 10ml thrice a day. Children 1 - 6 years: 5ml.
It should be taken well diluted with water, after meals. Shake the bottle before use.

Dosage Schedule
The dose may be taken three times a day.

4.3 Contraindications
Contraindicated in hyperkalaemia, renal dysfunction, ventricular arrhythmics and Addison's disease.

4.4 Special warnings and precautions for use
Mist. Potassium Citrate provides symptomatic relief only and is not anti-bacterial. Effective anti-bacterial therapy should be co-prescribed. It should be used with caution when renal or cardiac dysfunction is present.
Labels to state: if symptoms persist consult your doctor. Discard any unused mixture 2 months after opening.
Use with caution in the elderly
This medicine contains sodium benzoate per 10ml dose.

4.5 Interaction with other medicinal products and other forms of interaction
Concurrent administration of potassium-containing drugs, potassium sparing diuretics or other drugs that increase potassium levels (e.g. ACE inhibitors, ciclosporin, aliskiren) may lead to hyperkalaemia. May interact with cardiac glycosides. Citrates alkalinise the urine and thus may alter the urinary excretion of a number of drugs. This may lead to increased renal clearance of acidic drugs, such as salicylates, tetracylines and barbiturates, and prolongation of the half-life of basic drugs, such as sympathomimetics and stimulants. Particularly noteworthy is the diminished anti-bacterial activity of nitrofurantoin and methenamine.

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4.6 Fertility, pregnancy and lactation
No adverse effects are anticipated at recommended doses when used for initial symptomatic relief only. Treatment with potassium citrate mixture is adjunctive and secondary to anti-bacterial treatment of urinary tract infection.

4.7 Effects on ability to drive and use machines
No effect on mental alertness.

4.8 Undesirable effects
Mild nausea and occasionally vomiting may occur due to gastric irritation. Other side effects are those due to hyperkalaemia (if this occurs).

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 at: www.mhra.gov.uk/yellowcard.

4.9 Overdose
Overdosage is accompanied by nausea, vomiting, abdominal pain and symptoms due to hyperkalaemia and metabolic acidosis. Fluid and electrolyte balance together with ECG should be closely monitored. Treatment is symptomatic and supportive. Moderate to severe hyperkalaemia is a medical emergency requiring prompt correction.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Citrate and citric acid solutions are systematic and urinary alkalinizers thereby providing symptomatic relief of dysuria.

5.2 Pharmacokinetic properties
Potassium Citrate is absorbed and the citrate is metabolised to bicarbonate. Citric acid is metabolised to carbon dioxide and water. Oxidation is virtually complete with less than 5% of citrate being excreted unchanged in the urine.

5.3 Preclinical safety data
None

6. Pharmaceutical particulars

6.1 List of excipients
Sorbitol 70%
Sodium Methyl Paraben
Sodium Propyl Paraben
Sodium EDTA
Glycerin
Neotam
Sodium Saccharine
Flavor Lemon
Sodium Benzoate
Purified Water

Summary of Product Characteristics (SmPC)

6.2 Incompatibilities
Incompatible with calcium and strontium salts.

6.3 Shelf life
180 ml & 200ml: 24 months unopened

6.4 Special precautions for storage
Store below 30°C. Protect from light & moisture.

6.5 Nature and contents of container
200ml: Plastic bottle with white 28mm Plastic white cap.
180ml: Plastic bottle with white 28mm Plastic white cap.

6.6 Special precautions for disposal and other handling
None.

7. Marketing authorization holder

Krishat Pharma Industries Limited

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8. Manufacturer
Krishat Pharma Industries Limited
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