

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Citrate Mixture

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Citrate 1.5g/5ml.

Excipients with known effects

Sucrose 1.1g/5ml

Sodium benzoate (E211) 2.5mg/5ml

Ethanol 0.02mg/5ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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.

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. Contra-Indications

Contraindicated in hyperkalaemia, renal dysfunction, ventricular arrhythmics and Addison's Disease.

4.4 Special warnings and precautions for use

Potassium Citrate Mixture 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 product contains 1.1g of sucrose per 5ml dose. To be taken into account in people with diabetes. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains 2.5mg sodium benzoate per 5ml dose.

This medicine contains 0.02mg ethanol in each 5ml dose, which is equivalent to 0.46 vol%. The amount in each 5ml dose of this medicine is equivalent to less than 0.46ml beer or 0.18ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'.

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 alkalise 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, tetracyclines 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.

4.6. 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. Pre-clinical Safety Data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid Monohydrate (E330)

Quillaia Tincture

Lemon Oil Terpeneless

Ethanol (96%)
Sodium Benzoate (E211)
Purified Water
Syrup (sucrose)

6.2. Incompatibilities

Incompatible with calcium and strontium salts.

6.3 Shelf life

200ml: 36 months unopened

6.4. Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

200ml: Glass bottle with white 28mm polypropylene cap with tamper evident band and EPE/AL/Melinex liner.

6.6. Instruction for use and handling

None.

7. MARKETING AUTHORISATION HOLDER

L.C.M. Ltd.,
Linthwaite Laboratories
Huddersfield
HD7 5QH
England

8. MARKETING AUTHORISATION NUMBER

PL 12965/0031

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17.09.93 / 03.11.98

10. DATE OF REVISION OF THE TEXT

04/11/2020