SUMMARY OF THE PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCTS

K MAC ORAL SOLUTION (Potassium Citrate and Magnesium Citrate Oral Solution)

2. QUALITY AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Potassium citrate BP 1100 mg

Magnesium citrate USP 375 mg

3. PHARMACEUTICAL FORM

Dark brown coloured flavoured solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

K-Mac Oral Solution is indicated for:

- Prevention of recurrence of urinary stones
- Renal tubular acidosis (RTA) with calcium stones.
- Hypocitraturic calcium oxalate nephrolithiasis of any etiology
- Uric acid lithiasis with or without calcium stones
- Thiazide induced hypokalemia and hypomagnesemia in hypercalciuric nephrolithiasis • Relief from burning urination

4.2 Posology and method of administration

Three teaspoons (15ml) of K-Mac Oral Solution is diluted with one glass of water, after meals/ at bedtime or as directed by the physician.

Method of administration: Oral

4.3 Contraindications

K-Mac Oral Solution is contraindicated in:

Patients with hyperkalemia (or who have conditions predisposing them to hyperkalemia). Hyperkalemia is a condition caused by higher than normal levels of potassium in the bloodstream. A rise in serum potassium concentration may produce cardiac arrest. Such conditions include: chronic renal failure, uncontrolled diabetes mellitus, acute dehydration, strenuous physical exercise in unconditioned individuals, adrenal insufficiency, extensive tissue

breakdown, or the administration of a potassium-sparing agent (such as triamterene, spironolactone or amiloride).

Patients with active urinary tract infection (with either urea-splitting or other organisms, in association with either calcium or struvite stones). The ability of K-Mac oral solution to increase urinary citrate may be attenuated by bacterial enzymatic degradation of citrate. Moreover, the rise in urinary pH resulting from K-Mac Liquid therapy might promote further bacterial growth.

Patients with renal insufficiency (glomerular filtration rate of less than 0.7 ml/kg/min),because of the danger of soft tissue calcification

4.4 Special warnings and precautions for use General

Hyperkalemia:

In patients with impaired mechanisms for excreting potassium, potassium magnesium citrate administration can produce hyperkalemia and cardiac arrest. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium magnesium citrate in patients with chronic renal failure, or any other condition which impairs potassium excretion such as severe myocardial damage or heart failure, should be avoided.

Gastrointestinal Lesions:

Because of reports of upper gastrointestinal mucosal lesions following administration of potassium chloride (wax-matrix), and endoscopic examination of the upper gastrointestinal mucosa was performed in 30 normal volunteers after they had taken glycopyrrolate 2 mg. p.o. t.i.d., potassium citrate 95 mEq/day, wax-matrix potassium chloride 96 m Eq/day or wax matrix placebo, in thrice daily schedule in the fasting state for one week. Potassium citrate and the wax-matrix formulation of potassium chloride were indistinguishable but both were significantly more irritating than the wax-matrix placebo. In a subsequent similar study, lesions were less severe when glycopyrrolate was omitted. Solid dosage forms of potassium chloride have produced stenotic and/or ulcerative lesions of the small bowel and deaths. These lesions are caused by a high local concentration of potassium ions in the region of the dissolving tablets, which injured the bowel. In addition, perhaps because wax-matrix preparations are not enteric-coated and release some of their potassium content in the stomach, there have been reports of upper gastrointestinal bleeding associated with these products. The frequency of gastrointestinal lesions with wax-matrix potassium chloride products is estimated at one per 100,000 patient years. Experience with potassium citrate is limited, but a similar frequency of gastrointestinal lesions should be anticipated.

Renal impairment:
Potassium magnesium citrate is contraindicated in patients with renal insufficiency (glomerular filtration rate of less than 0.7 ml/kg/min), because of the danger of soft tissue calcification and increased risk for the development of hyperkalemia.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration of potassium magnesium citrate and a potassium-sparing diuretic (such as triamterene, spironolactone or amiloride) should be avoided, since the simultaneous administration of these agents can produce severe hyperkalemia.

4.6 Pregnancy and lactation

Pregnancy: Animal reproduction studies have not been conducted with potassium magnesium citrate. It is also not known whether potassium magnesium citrate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium magnesium citrate should be given to a pregnant woman only if clearly needed.
Lactation: The normal potassium ion content of human milk is about 13 mEq/l. It is not known if potassium magnesium citrate has an effect on this content. Caution should be exercised when potassium magnesium citrate is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

No effect on mental alertness.

4.8 Undesirable effects

Minor gastrointestinal complaints, such as abdominal discomfort, vomiting, diarrhea, loose bowel movements or nausea. These symptoms are due to the irritation of the gastrointestinal tract, and may be alleviated by taking the dose with meals or snack or by reducing the dosage. Patients may find intact matrices in feces.

4.8 Overdose

The administration of potassium salts to persons without predisposing conditions for hyperkalemia rarely causes serious hyperkalemia at recommended dosages. It is important to

recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electro cardiographic changes (peaking of T-wave, loss of P-wave, depression of S-T segment and prolongation of the QT interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest. Treatment measures for hyperkalemia include the following: (1) elimination of potassium-rich foods, medications containing potassium and of potassium-sparing diuretics, (2) intravenous administration of 300-500 ml/hr of 10% dextrose solution containing 10-20 units of insulin/1000 ml, (3) correction of acidosis, if present, with intravenous sodium bicarbonate and (4) use of exchange resins, hemodialysis or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Potassium Magnesium Citrate when given orally, the metabolism of absorbed citrate produces an alkaline load which increases urinary pH and raises urinary citrate. In addition to raising urinary pH and citrate, potassium magnesium citrate increases urinary potassium and magnesium by approximately the amount contained in the medication. In some patients, potassium citrate causes a transient reduction in urinary calcium. The changes induced by potassium citrate produce a urine that is less conducive to the crystallization of stone-forming salts (calcium oxalate, calcium phosphate and uric acid). Increased citrate in the urine, by complexing with calcium, decreases calcium ion activity and thus the saturation of calcium oxalate. Increased magnesium in the urine, by complexing with oxalate decreases the oxalate ion activity and thus the saturation of calcium oxalate.

Citrate and magnesium also inhibits the spontaneous nucleation of calcium oxalate and calcium phosphate (brushite). The increase in urinary pH also decreases calcium ion activity by increasing calcium complexation to dissociated anions. The rise in urinary pH also increases the ionization of uric acid to more soluble urate ion.

Potassium citrate therapy does not alter the urinary saturation of calcium phosphate, since the effect of increased citrate complexation of calcium is opposed by the rise in pH-dependent dissociation of phosphate. Calcium phosphate stones are more stable in alkaline urine. In the setting of normal renal function, the rise in urinary citrate following a single dose begins by the first hour and lasts for 12 hours. With multiple doses the rise in citrate excretion reaches its peak

by the third day and averts the normally wide circadian fluctuation in urinary citrate, thus maintaining urinary citrate at a higher, more constant level throughout the day.

5.2 Pharmacokinetic properties Magnesium citrate:

Absorption: Up to 20% magnesium citrate is absorbed.

Elimination: Magnesium citrate is excreted by renal elimination.

Onset is 0.5 to 5 h.

Potassium citrate:

Potassium citrate is metabolized to potassium bicarbonate, thus acting as systemic alkalizers.

5.3 Preclinical safety data

N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

S. No	Name of the Ingredients	Reference
1.	Sorbitol solution 70% (Non-crystallising)	BP
2.	Sodium Benzoate	BP
3.	Saccharin Sodium	BP
4.	Citric Acid Monohydrate	BP
5.	Caramel	IHS
6.	Mixed fruit S1038	IHS
7.	Purified Water	BP

Approved chemical name	Specification	Quantity/ 5 ml (mg)	Reason for inclusion
Potassium Citrate	BP	1100.00	Active

Magnesium Citrate	USP	375.00	Active
Sorbitol solution 70% (Non-crystallising)	BP	1000.00	Diluent
Sodium Benzoate	BP	10.00	Antimicrobial preservative
Saccharin Sodium	BP	10.00	Sweetening agent
Citric Acid Monohydrate	BP	230.25	Acidifying agent
Caramel	IHS	15.00	Colouring agent
Mixed fruit S1038	IHS	0.03	Sweetening agent
Purified Water	BP	Q.S to 5 ml	Solvent

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

24 months

6.4 Special Precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

Nature: Amber coloured PET bottle sealed with 25 mm ROPP cap provided along with 15 ml transparent measure cup and a product information literature

Contents of container: 200ml **6.6**

Special precautions for disposal

No special requirements.

7 - MARKETING AUTHORIZATION HOLDERAND MANUFACTURING SITE ADDRESSES:

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8 - **MARKETING AUTHORISATION NUMBER(S)**

FDA/SD.193-2083

9 - **DATE OF FIRST AUTHORISATION/RENEWALOF AITHORIZATION**

March 2022

10 - **DATE OF REVISION OF THE TEXT**

August 2025