RC: 1672214

Jehyson HEALTHCARE LIMITED

SUMMARY OF PRODUCT CHARACTERIZATION (SMPC) FOR JEHYSON MIST POTASSIUM CITRATE

1. Name of the medicinal product

Jehyson Mist Potassium Citrate

2. Qualitative and quantitative composition

Each 10ml Contains

Potassium Citrate 3.0 g

Citric Acid 0.50g

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid

4. Clinical particulars

4.1 Therapeutic indications

Potassium Citrate and Citric Acid Oral Solution is an effective alkalinizing agent useful in those conditions where long-term maintenance of an alkaline urine is desirable, such as in patients with uric acid and cystine calculi of the urinary tract, especially when the administration of sodium salts is undesirable or contraindicated. In addition, it is a valuable adjuvant when administered with uricosuric agents in gout therapy, since urates tend to crystallize out of an acid urine. It is also effective in correcting the acidosis of certain renal tubular disorders where the administration of potassium citrate may be preferable. This product is highly concentrated, and when administered after meals and before bedtime, allows one to maintain an alkaline urinary pH around the clock, usually without the necessity of a 2 A.M. dose. This product alkalinizes the urine without producing a systemic alkalosis in recommended dosage. It is highly palatable, pleasant tasting and tolerable, even when administered for long periods. Potassium citrate does not neutralize the gastric juice or disturb digestion.

4.2 Posology and method of administration

Orally

Adults:

Three times daily for two days.

Elderly

As adults

Children

Not recommended for children under six years of age. For children over six years of age use adult dosage.

4.3 Contraindications

There are no specific contraindications but use with caution in patients with impaired renal function or cardiac disease.

4.4 Special warnings and precautions for use

Intended for short term treatment. Patients should seek doctor's advice if symptoms persist after 48 hours treatment.

This product also contains aspartame, a source of phenylalanine. This may be harmful to people with phenylketonuria. This medicine contains less than 1mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of the following drugs may lead to hyperkalaemia: potassium sparing diuretics, ACE inhibitors, aliskiren, angiotensin-II receptor antagonists, ciclosporin and tacrolimus. Avoid concomitant use with methenamine. The activity of cardiac glycosides is to some extent dependent upon serum potassium levels. Therefore, there is a possible interaction and caution is advised.

4.6 Pregnancy and lactation

There is no, or inadequate epidemiological evidence of safety of the ingredients of Cystopurin sachets in human pregnancy but they have been in wide use for many years without apparent ill consequence. If drug therapy is needed in pregnancy, this drug can be used if there is no safer alternative. However, pregnant women should be advised to seek medical advice on the treatment of cystitis rather than using OTC medicines.

4.7 Effects on ability to drive and use machines

There is no evidence to suggest that the ability to drive or to use machines of the patient will be affected.

4.8 Undesirable effects

Potassium Citrate and Citric Acid Oral Solution is generally well tolerated without any unpleasant side effects when given in recommended doses to patients with normal renal function and urinary output. However, as with any alkalinizing agent, caution must be used in certain patients with abnormal renal mechanisms to avoid development of hyperkalemia or alkalosis. Potassium intoxication causes listlessness, weakness, mental confusion, tingling of extremities, and other symptoms associated with a high concentration of potassium in the serum. Periodic determinations of serum electrolytes should be carried out in those patients

with renal disease in order to avoid these complications. Hyperkalemia may exhibit the following electrocardiographic abnormalities: Disappearance of the P wave, widening and slurring of QRS complex, changes of the S-T segment, tall peaked T waves, etc.

4.9 Overdose

Hyperkalaemia may occur on prolonged high dosage. (Each Cystopurin sachet contains 27.8 mmol K+). This may be controlled by a number of methods including the use of calcium gluconate, glucose or glucose and insulin, sodium bicarbonate, cationic exchange resins, haemodialysis or peritoneal dialysis.

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

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Mannitol

Citric Acid

Aspartame

Natural flavoring

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30° C.

6.5 Nature and contents of container

200ml amber colour pet bottle capped with 28mm Ropp Cap

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

Jehyson Crescent, Km 78, Lagos-Abeokuta

Expressway, Apomu Ewekoro LGA,

Ogun State.