SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cystopurin

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Citrate 3.0 g

Excipient(s) with known effect:

Aspartame (E951) 40 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sachet containing a pink-brown granular powder.

Clinical particulars

4.1 Therapeutic indications

For the symptomatic relief of mild urinary tract infections (cystitis).

4.2 Posology and method of administration

Orally: Dissolved in water.

Adults:
One 3g sachet, dissolved in 200mls of cold water, three times daily for two days. All six sachets must be taken to complete the treatment.

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 Contra-indications

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 Interactions with other medicaments and other forms of interactions

Concurrent administration of the following drugs may lead to hyperkalaemia: potassium sparing diuretics and aldosterone antagonists, 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 Fertility, 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

Some patients may experience mild diuresis.
Potassium salts may give rise to gastric irritation, the effects of which may be minimised by diluting sachet contents well with water. Doses may also be given with or after meals.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose symptoms, emergency procedures, antidotes

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.

Pharmacological properties

5.1 Pharmacodynamic properties

Potassium citrate after absorption is metabolised and renders the urine less acid. A mild diuresis usually follows treatment with potassium citrate.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)
Citric Acid (Anhydrous)
Aspartame (E951)
Natural flavouring Cranberry type 14666: Maltodextrin, Natural Flavouring Substances, Flavouring Preparations (including natural cranberry juice concentrate*), Silicon Dioxide (E551), Carmine* (E120), Triacetin (E1518).

*contain trace amounts of sodium, see section 4.4.

6.2 Major incompatibilities

None stated.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25 C.

6.5 Nature and contents of container

Hermetically sealed foil laminate sachet.
Pack sizes: 6 sachets.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way
Reading
RG2 6AD

8. Marketing authorisation number

PL 00010/0322

9. Date of the first authorisation or renewal

01/09/2005

10 DATE OF REVISION OF THE TEXT

05/03/2021