Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cystopurin 3g Granules for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 3g of Potassium Citrate

Excipients - contains aspartame (E951) 0.04g/sachet.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral solution.

Pink-brown granules for dissolution in water.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology
Adults (including the elderly and children over 6 years):
One 3 g sachet, dissolved in 200 ml of cold water, three times daily for two days. All six sachets must be taken to complete the treatment.

Paediatric population
Not recommended for children under six years of age.

Method of administration
For oral administration.

4.3 Contraindications

Use in patients with renal insufficiency.

4.4 Special warnings and precautions for use

This product is intended for short term treatment. Patients should seek doctor's advice if symptoms persist after 48 hours treatment.

This product should only be used with caution in patients with cardiac disease.

This product contains a source of phenylalanine. May be harmful for people with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of potassium sparing diuretics or ACE inhibitors may lead to hyperkalaemia. The activity of cardiac glycosides is to some extent dependant upon serum potassium levels. Therefore, there is a possible interaction and caution is advised.

4.6 Fertility, pregnancy and lactation

There is no information available from animal studies and there is no 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

None.

4.8 Undesirable effects

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 HPRA Pharmacovigilance; Website: www.hpra.ie.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: potassium ATC code: A12BA02

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

5.2 Pharmacokinetic properties

Potassium citrate is metabolised, after absorption, to bicarbonate. Bicarbonate ions are excreted in the urine, which is rendered alkaline, and there is an accompanying diuresis.

5.3 Preclinical safety data

None available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)
Citric Acid (Anhydrous) (E330)
Aspartame (E951)
Natural flavouring Cranberry type 14666:
maltodextrin, natural flavouring substances, flavouring preparations, silicon dioxide (E551), carmine (E120), triacetin (E1518).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Hermetically sealed paper/foil/polythene laminate sachets contained in a cardboard outer carton. Each carton contains 6 sachets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA1410/042/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th September 1995

Date of latest renewal: 19th September 2010

10 DATE OF REVISION OF THE TEXT

November 2022