

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA1410/042/001

Case No: 2043417

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Transferred from PA0021/065/001.

Bayer Limited

The Atrium, Blackthorn Road, Dublin 18, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Cystopurin 3g Granules for oral solution.

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **21/11/2008** until **18/09/2010**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cystopurin 3g granules for oral solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Citrate 3 g/sachet.

For 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

For oral administration.

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.

Not recommended for children under six years of age.

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.

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 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.

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)

*Flavour cranberry durarome

**Flavour cranberry juice

Aspartame (E951)

*Flavour cranberry Durarome:

(Natural flavouring substances, flavouring preparations, maltodextrin, sugar, glycerol, triacetate, E322, ethyl alcohol, E551).

**Flavour cranberry juice:
(Flavourings derived from cranberry extract, maltodextrin).

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

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

Bayer Ltd
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1410/42/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th September 1995

Date of last renewal: 19th September 2005

10 DATE OF REVISION OF THE TEXT

November 2008