

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cystopurin 3g Granules for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Citrate 3g/sachet

Also contains aspartame (E951).

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Granules for Oral Solution

Product imported from the UK:

Pink-brown granules for dissolution in water.

4 CLINICAL PARTICULARS

As per PA1410/042/001.

4.2 Posology and method of administration

4.3 Contraindications

4.4 Special warnings and precautions for use

4.8 Undesirable effects

4.9 Overdose

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/042/001.

5.3 Preclinical safety data

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)

Citric acid (E330)

Aspartame (E951) (a source of phenylalanine)

Cranberry flavour

(flavour contains natural cranberry extracts with maltodextrin, silicon dioxide (E551), carmine (E120) and triacetin (E1518)).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the sachets and outer package of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original carton.

6.5 Nature and contents of container

Over-labelled outer carton containing sachets.

Pack size 6.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/144/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 2011

10 DATE OF REVISION OF THE TEXT

February 2020