

1. NAME OF THE MEDICINAL PRODUCT

Cystitis Relief

Care Cystitis Relief 4g granules for oral solution

Cystocalm 4g granules for oral solution

Cymalon 4g Granules for Oral Solution

CanesOasis Cystitis Relief 4g granules for oral solution

Sainsbury's Healthcare Cystitis Relief 4g Granules for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Citrate Dihydrate BP 4.0g

3 PHARMACEUTICAL FORM

Granules to be reconstituted for oral administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of the symptoms of cystitis in women.

4.2 Posology and method of administration

Adult women: The contents of one sachet dissolved in a glass of water, to be taken three times a day for two days.

Men and children: Not recommended.

4.3 Contraindications

Patients with diabetes, heart disease, hypertension, history of renal disease or those on a low salt diet.

During pregnancy and lactation.

4.4. Special Warnings and Special Precautions for Use

If symptoms persist after the two day course of treatment is completed, medical attention should be sought. Do not exceed the stated dose. Keep out of the sight and reach of children.

4.5. Interactions with other Medicinal Products and other forms of Interaction

Sodium containing preparations should be avoided by patients on lithium because sodium is preferentially absorbed by the kidney resulting in increased lithium excretion and reduced plasma levels.

Urinary alkalinisers should not be used with hexamine because it is only effective in acid urine.

The effects of a number of drugs may be reduced or increased by the alkalinisation of the urine and reduction in gastric pH brought about by the active ingredients in the product.

4.6 Pregnancy and lactation

Contraindicated during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None stated.

4.8. Undesirable Effects

Mild diuresis.

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.

4.9. Overdose Symptoms, Emergency Procedures, Antidotes

In the unlikely event of overdosage occurring with this product, treatment should be symptomatic.

Excessive administration of sodium citrate may cause gastrointestinal discomfort and diarrhoea. Excessive doses of sodium salts may lead to sodium overloading and hyperosmolality. Excessive administration of bicarbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Treatment is symptomatic and consists of appropriate correction of fluid and electrolyte balance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The effect of sodium citrate is to render the urine less acidic.

5.2 Pharmacokinetic properties

None relevant.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose BP (1.5g)

Colloidal Silicon Dioxide BP

Saccharin Sodium BP

Cranberry Flavouring

6.2 Incompatibilities

None stated.

6.3 Shelf life

The granules have a three year shelf life.

The reconstituted solution should be used immediately.

6.4 Special precautions for storage

Store below 25°C, in dry place.

6.5 Nature and contents of container

Foil laminate sachets

or

paper (outer surface layer) /polyethylene (outer layer) /aluminium foil (outer layer) /ionomer resin (inner layer) sachets

Each sachet contains 5.575 g of granule enclosed in a cardboard outer.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Ltd

Wrafton

Braunton

North Devon

EX33 2DL

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 12063/0045

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

29/11/1996 / 04/12/2003

10 DATE OF REVISION OF THE TEXT

16/11/2015