Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cymalon granules for oral solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cymalon sachet contains:

Citric acid (anhydrous)	1063.0	mg
Sodium bicarbonate	1200.0	mg
Sodium citrate dihydrate	2819.0	mg
Sodium carbonate	130.0	mg
Combined alkalinity to	4.4	g Sodium citrate

Excipients with known effect:
Contains sucrose 1.5g and sodium 1046mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral solution.

Particles ranging in colour from white to yellow, which disperse in water with slight effervescence yielding a lemon flavoured solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Cymalon is an alkalinising agent indicated for the relief of symptoms due to cystitis in adult females only.

4.2 Posology and method of administration

Posology

Adults
One sachet to be taken in water, three times a day over 48 hours.

Paediatric population
Cymalon is not recommended for children.

Method of administration

Cymalon granules are to be administered orally after dissolution in water.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Use in patients with symptoms and signs of significant bacteriuria.

Cymalon should not be used in pregnancy or lactation, or in patients with heart disease, hypertension, diabetes or a history of renal disease.

4.4 Special warnings and precautions for use

Patients should be advised against repeated use. If symptoms persist 48 hours after treatment is completed you are advised to consult your doctor.
Cymalon treatment should not need to be repeated often. If symptoms come back frequently, consult your doctor.

Sodium
This medicinal product contains 1046 mg of sodium per sachet. To be taken into consideration by patients on a controlled sodium diet.

Sucrose
Contains sucrose also. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-insomaltase insufficiency should not take this medicine.

Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interaction

Sodium-containing preparations should be avoided by patients on lithium because they enhance the excretion of lithium and reduce lithium plasma levels.

Urinary alkalinisers should not be used with methenamine 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 this product.

4.6 Fertility, pregnancy and lactation

Do not use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Sodium bicarbonate may cause flatulence.

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, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

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 consists of appropriate correction of fluid and electrolyte balance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

G0B4 – Other Urologicals, incl. Antispasmodics.

Sodium bicarbonate increases the alkali reserve of the plasma and increases excretion of urine, which is rendered less acidic.

Sodium citrate is used to make the urine alkaline in the treatment of urinary tract infections.

Citric acid increases the secretion of urine and renders it less acidic. It is also used in the preparation of effervescent granules to aid effervescence.

5.2 Pharmacokinetic properties

Cymalon is administered in the form of a solution.

5.3 Preclinical safety data

No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Saccharin sodium
Natural lemon flavour (F309)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years (unopened).
Drink immediately after reconstitution.

6.4 Special precautions for storage

Keep in the original package.

6.5 Nature and contents of container

Cymalon granules are packed into low-density polythene, aluminium foil and paper (PFP) laminate sachets, each containing 6.76 g granules.

These are further packed into cardboard cartons each containing 6 sachets.

6.6 Special precautions for disposal and other handling

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
Reykjavíkurvegi 76-78
220 Hafnarfjordur
Iceland

8 MARKETING AUTHORISATION NUMBER

PA1380/051/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th February 1989
Date of last renewal: 22nd April 2009

10 DATE OF REVISION OF THE TEXT

July 2015