

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Cymalon

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of 6.76g of granules contain the following actives:

Citric Acid (anhydrous) EP	1063.00mg
Sodium Citrate dihydrate EP	2819.00mg
Sodium Carbonate EP	130.00mg
Sodium Bicarbonate EP	1200.00mg

### 3 PHARMACEUTICAL FORM

Granules for solution.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

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

#### 4.2 Posology and method of administration

Route of administration: Oral

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

Children Cymalon is not recommended for children.

#### 4.3 Contraindications

Cymalon should not be taken in cases of pregnancy, heart disease, high blood pressure, any form of kidney disease or whenever a restricted salt intake is indicated.

#### 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. Do not exceed the stated dose. Keep out of the reach of children.

#### 4.5 Interaction 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**

Do not use during pregnancy and lactation.

#### **4.7 Effects on ability to drive and use machines**

None stated.

#### **4.8 Undesirable effects**

Sodium bicarbonate may cause flatulence.  
Mild diuresis may occur.

#### **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 is symptomatic and consists of appropriate correction of fluid and electrolyte balance.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

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**

Not applicable.

### **6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Castor Sugar EP  
Saccharin Sodium BP  
Flavour Lemon Natural (F309)

**6.2 Incompatibilities**

There are no known records of incompatibilities.

**6.3 Shelf life**

36 months

**6.4 Special precautions for storage**

Protect from moisture.

**6.5 Nature and contents of container**

Cymalon granules are packed into low density polythene, aluminium foil and paper (PPFP) laminate sachets, each containing 6.76g granules. These are further packed into cardboard cartons each containing 6 sachets.

**6.6 Special precautions for disposal**

Not applicable.

**7 MARKETING AUTHORISATION HOLDER**

Actavis Group PTC ehf  
Reykjavíkurvegi 76-78  
220 Hafnarfjörður  
Iceland.

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 30306/0066

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

22 July 2002

**10 DATE OF REVISION OF THE TEXT**

**11 DOSIMETRY (IF APPLICABLE)**

**12 INSTRUCTIONS FOR PREPARATION OF  
RADIOPHARMACEUTICALS (IF APPLICABLE)**