Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ACC 100 mg Granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of ACC 100 mg granules contains Acetylcysteine 100 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Granules
White granules with an odour and taste of orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

ACC is indicated as an adjunct in the treatment of chronic bronchitis or other respiratory conditions associated with the excessive production of viscous mucous.

4.2 Posology and method of administration

Route of Administration:
Oral.

Recommended Dosage Schedule:

Acute therapy - Adults (over 14 years):
2 sachets (200 mg) 3 times daily.

Children 2-6 years:
Two sachets (200 mg) 2 times daily.

Infants under 2 years:
Two sachets (200 mg) daily.

The granules should be dissolved in a glass of water.

In acute exacerbations a treatment period of 5-10 days is usually adequate but may be extended if necessary. In chronic bronchitis relief of symptoms may be noticeable after treatment for 1-2 months but treatment may be extended for up to six months, e.g. during winter season. When oral antibiotics or drugs are required they should be administered 2 hours apart from Acetylcysteine.

4.3 Contraindications

ACC is contra-indicated in patients who are hypersensitive to acetylcysteine and in patients with active peptic ulceration.

4.4 Special warnings and precautions for use

Each sachet contains the equivalent of 2.8 g of sucrose. This should be taken into account when treating diabetic patients. ACC should be given to new-born infants only if absolutely necessary.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

ACC should not be administered with oral antibiotics with the exception of amoxycillin, cefuroxim, doxycycline, erythromycin and thiamphenicol.

The concomitant administration of ACC with oral antibiotics results in reduction of the effectiveness of the antibiotics. Antibiotics should be taken at least 2 hours before or 2 hours after taking ACC.

4.6 Pregnancy and lactation

ACC granules should not be administered in pregnancy or during lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Nausea, heartburn, vomiting, urticaria, headache and tinnitus have infrequently been reported, but these rarely necessitate the withdrawal of treatment.

Allergic skin reactions (itching and urticaria) and bronchospasm, especially in asthmatic patients, have been reported rarely in patients taking oral acetylcysteine. High doses of acetylcysteine given intravenously have caused anaphylactoid reactions.

4.9 Overdose

There is no specific antidote for acetylcysteine and treatment is symptomatic. It consists of postural drainage, bronchial suction and supportive therapy is indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Acetylcysteine has an intense mucolytic action on mucoid and mucopurulent secretions due to its inability to split disulphide bonds in mucous glycoprotein. This property allows it to be used as adjuvant therapy in many clinical conditions characterised by the presence of viscous mucoid or mucopurulent secretions particularly in the respiratory tract.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Ascorbic Acid
Saccharin Sodium
Orange Flavour Dry
1:1000 Sotteri 289

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf-life for ACC 100 mg granules is 3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in the original package to protect from moisture.

6.5 Nature and contents of container

ACC 100 mg granules are packed in thermo-sealed sachets made of a triple layer foil of aluminium - paper polythene. The 80 x 49 mm sachets are packed in outer cardboard cartons.

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

Rowex Ltd.
Bantry
Co. Cork

8 MARKETING AUTHORISATION NUMBER

PA 711/7/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 December 1998

Date of last renewal: 21 December 2003

10 DATE OF REVISION OF THE TEXT

March 2004