

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ACC 600 mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 600 mg Acetylcysteine Ph.Eur.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablet.

White, round, smooth tablets, having a smell of blackberries.

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:

The tablets should be dissolved in about a half a glass of water.

Adults:

1 effervescent tablet daily preferably in the evening.

4.3 Contraindications

ACC is contra-indicated in patients who are hypersensitive to acetylcysteine and in patients with active ulceration. ACC 600 mg Effervescent Tablets should not be given to children under 14 years of age.

4.4 Special warnings and special precautions for use

ACC should be given to newborn infants only if absolutely vital.

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, cefuroxime, 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 Effervescent Tablets 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 ability 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

Citric Acid Anhydrous
Sodium Hydrogen Carbonate
Sodium Carbonate, Anhydrous
Mannitol
Lactose Anhydrous
Ascorbic Acid
Sodium Cyclamate
Saccharin Sodium
Sodium Citrate
Blackberry Flavour “B”

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Aluminium tubes with polyethylene stopper, containing 25 tablets and a desiccant.

6.6 Instructions for use and handling

No specific requirements.

7 MARKETING AUTHORISATION HOLDER

ROWEX LTD
Bantry
Co. Cork

8 MARKETING AUTHORISATION NUMBER

PA 711/7/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2002

10 DATE OF REVISION OF THE TEXT

November 2002