Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ACC 200 mg Capsules.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Acetylcysteine 200 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Hard Capsule.

White, opaque, hard gelatin capsule, filled with a white to off white powder.

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 adminstration

Route of Administration:
Oral.

Recommended Dosage Schedule

Acute Therapy – Adults (over 14 years):
The usual dose is three capsules (3 x 200 mg) daily.

Children 6-14 years:
The usual dose is two capsules (2 x 200 mg) daily.

Chronic Therapy – Adults (over 14 years):
The usual daily dose is two capsules (2 x 200 mg).

Mucoviscidosis – Children over 6 years:
The usual dose is three capsules (3 x 200 mg) daily.

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 special 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.

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 Capsules 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

Pharmacotherapeutic classification (Group + ATC code):
R05C B01
Respiratory System, Cough & Cold preparations, Mucolytics, Acetylcysteine

R05C B01
Sensory Organs, Ophthalmologicals, Other ophthalmologicals, Acetylcysteine

V03A B23
Various, All other therapeutic antidotes, Acetylcysteine

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

Mannitol
Colloidal Anhydrous Silica
Stearic Acid

Shell excipients:
Gelatin
Titanium Dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

ACC 200 mg Capsules are packed in PVC/Aluminium blisters. The capsules are available in packs of 6, 30 and 100 capsules. Not all pack sizes may be marketed.

6.6 Instructions for use and handling

No specific instructions required.

7 MARKETING AUTHORISATION HOLDER

Rowex Ltd
Bantry
County Cork

8 MARKETING AUTHORISATION NUMBER

PA 711/7/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th November 1996
Date of last renewal: 7th November 2001

10 DATE OF REVISION OF THE TEXT

March 2002