IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA1441/001/001
Case No: 2051163

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Zambon S.p.A.

via Lillo del duca, 10, **20091-Bresso**, **Milano**, **Italy**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Fluimucil 200 mg granules for oral solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **09/10/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fluimucil 200 mg granules for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient - Acetylcysteine 200 mg.

Each Fluimucil sachet contains the equivalent of 2.7 g of sucrose.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral solution
Orange granules for oral solution contained in sachets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

FLUIMUCIL is indicated in acute and chronic bronchitis and other respiratory conditions associated with the production of viscous mucus. FLUIMUCIL is also indicated for use in patients with abdominal complications associated with cystic fibrosis.

4.2 Posology and method of administration

FLUIMUCIL is for oral administration. The granules should be dissolved before administration in a glass of water.
The recommended posology is described below.

RESPIRATORY CONDITIONS

Children up to 2 years:	1 sachet (200 mg) daily.
Children of 2-6 years:	1 sachet (200 mg) twice daily.
Adults:	1 sachet (200 mg) three times daily.
Elderly:	There is no evidence to suggest that the dosage should be different.

In acute cases a treatment period of 5-10 days is usually adequate but may be extended if necessary. In chronic bronchitis relief of symptoms may be continued for up to 6 months, e.g. during the winter season.

CYSTIC FIBROSIS

Children up to 2 years:	½ sachet (100 mg to 200 mg) three times daily.
Children of 2-6 years-.	1 sachet (200 mg) three times daily.
Adults:	1 or 2 sachets (200 or 400mg) three times daily. In adults a higher starting dose of 4 sachets (800 mg) three times daily is recommended for the acute treatment of abdominal complications associated with cystic fibrosis and, in severe cases, doses of up to 18g acetylcysteine have been used and were well tolerated.

4.3 Contraindications

Hypersensitivity to acetylcysteine.

4.4 Special warnings and precautions for use

Each FLUIMUCIL sachet contains the equivalent of 2.70 g sucrose. This should be taken into account when treating diabetic patients.

4.5 Interaction with other medicinal products and other forms of interaction

FLUIMUCIL can be administered concurrently with amoxycillin, doxycillin and erythromycin. When other oral antibiotics or drugs are required, they should be administered 1-2 hours apart from FLUIMUCIL.

4.6 Pregnancy and lactation

The administration of acetylcysteine during pregnancy is advised only if there are compelling reasons.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Nausea, heartburn, vomiting, urticaria, headache and tinnitus have infrequently been reported but these rarely necessitate withdrawal of treatment. Allergic skin reactions 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 supporting therapy as indicated.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Acetylcysteine possesses anti-oxidant and mucolytic properties. In addition to regulating the production of mucus, it has a direct lytic action on mucus structure.

5.2 Pharmacokinetic properties

In patients with respiratory disorders, orally administered acetylcysteine is rapidly absorbed (T1/2= 2 to 3 hours) and not only reaches the lungs (47% of the dose has been recorded in the lungs 5 hours after administration) but passes directly into bronchial mucus.

5.3 Preclinical safety data

NAC is characterised by particular low toxicity. LD50 in rats is higher than 10 g/kg when NAC is orally administered.

In prolonged treatments a dosage of 1g/kg/day orally has been well tolerated in rats for 12 weeks. In dog the oral administration of 300 mg/kg/day for the duration of 1 year has not determined toxic reactions.

High dose treatment in pregnant rats and rabbits has not determined the birth of subjects with any malformations.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin
Orange flavour
Granulate of orange juice
Sucrose

6.2 Incompatibilities

The addition of other drugs to the FLUIMUCIL solution should be avoided.

6.3 Shelf Life

Unopened: three years.
After dissolution: use immediately.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the sealed sachet as provided, in order to protect from light.

6.5 Nature and contents of container

Sachets consist of paper-aluminium-polyethylene. Sachets are supplied in cardboard outer box containing 30 sachets.

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

The dose should be dissolved before administration in a glass of water immediately after opening the sachet.

The medicine should not be used if the sachet is damaged in any way.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

ZAMBON S.p.A.
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20091 Bresso (MI)
Italy

8 MARKETING AUTHORISATION NUMBER

PA 1441/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th July 1983

Date of last renewal: 20th July 2008

10 DATE OF REVISION OF THE TEXT

October 2008