**Patient’s leaflet**

**FLUIMUCIL®**

Granulate/Effervescent tablets/Syrup ready for the use

**Mucolytic.**

**Composition**

Active ingredient: N-acetylcysteine
Granulate as 1400, 200 and 600 mg N-acetylcysteine sachets
Effervescent tablets, 200 and 600 mg N-acetylcysteine

**Properties / Effects**

Fluimucil contains the active ingredient N-acetylcysteine, a cysteine derivative with a reactive free thiol group, possessing both mucolytic and antioxidant properties. The mucolytic action of N-acetylcysteine is based on the direct N-acetylcysteine and indir glutathione inactivating action on electrophilic and oxidant compounds.

Through cysteine, N-acetylcysteine makes available an essential glutathione synthesis precursor, with a consequent increase in glutathione endogenous supplies. Exogenous and endogenous oxidants, that can be neutralized by N-acetylcysteine and glutathione, have in fact a role in the pathogenesis of inflammatory respiratory airways disease.

**Pharmacokinetics**

**Absorption**

N-acetylcysteine absorption after oral administration is prompt and complete.

**Distribution**

N-acetylcysteine is principally spread within the aqueous environment of the extracellular space. It can be localized mainly at level of the liver kidneys, lungs and bronchial mucus.

**Metabolism**

The metabolism process starts soon after the product administration: N-acetylcysteine is deacetylated at level of the intestinal wall and upon its first liver passage to L-cysteine and then metabolized to inactive bonds.

**Elimination**

About 30% of the administered dose is eliminated directly by renal excretion.

**Indications /Possibilities of use**

All respiratory airways diseases, causing formation of a dense secretion that cannot be can only partially be expectorated, such as acute and chronic bronchitis, laryngitis, sinusitis, tracheitis, influenza, bronchial asthma and (as complementary treatment) mucoviscidosis.

**Posology /Instruction for use**

**Usual dosage for acute diseases**

- Children from 1 to 2 years of age: 2.5 ml syrup ready for the use 3 times/day
- Children from 2 to 12 years of age: 300-400 mg daily, one 100 mg sachet or 5 ml syrup ready for the use 3 times/day or one 200 mg effervescent tablet twice a day.
- Children beyond 12 years of age and adults: 600 mg/day, divided into one (600 mg effervescent tablet or sachet, preferably in the evening) or more administrations (e.g. 200 or 10 ml syrup ready for the use 3 times/day)

**Special dosage instructions**

- Children: In children with age ranging between 1 and 2 years, Fluimucil must be administrated only under medical prescription, whilst for suckling and children below 1 year of age, a steady medical surveillance within a hospital environment is required.
- Long-term treatment: 400 mg/day, divide into 2 administrations; the maximum treatment duration ranges between 3 and 6 months.
- Should the excessive mucus production and the relevant cough not disappear after a 2–week treatment, then the diagnosis is to be appropriately checked by the physician, who has to examine the possible cause of such persistence, so as to exclude, for example, a malignant respiratory airways disease.

**Mucoviscidosis:** as above, but for children from 6 years of age one 200 mg sachet or 10 ml syrup ready for the use 3 times/day, or one 6 mg effervescent tablet or granulate sachet on day.

Dissolve the content of one sachet or effervescent tablet into a glass of cold or warm water. It is not suggested to dissolve Fluimucil concomitantly with other medicines.

The slight sulphur odor that could be perceived upon sachet or blister opening, evaporates rapidly, and has no influence of the preparative efficacy.

**Use restrictions**

**Contraindications**

The product must not be administered in case of:
- Active peptic ulcer
- Ascertained hypersensitivity to N-acetylcysteine.
Syrup ready for the use: children below 12 years of age (for children with mucoviscidosis: below 6 years of age) - Concomitant use of an antitussive is medically not appropriate (see "Precautions"

**Precautions**

Special caution is required for patients with risk of gastrointestinal bleeding (e.g. with latesletic ulcer of esophagus varices), since Nacetylcystein oral administration can induce vomiting.

Owing to the risk of bronchospasm, special caution is required for patients suffering from bronchial asthma or with hyperreactive bronchial system.

In case of onset of hypersensitivity reactions bronchospasm, the product administration must be immediately discontinued, and appropriate therapeutic measures are to be avoided, as they suppress the cough reflex and the physiologic self-cleaning mechanism of respiratory airways, thus causing a mucus stasis with possible risk of bronchospasm an respiratory airways infections (see "Contraindications").

Subjects suffering from hypertension, for whom the salt use is precluded, must consider that each 200 and 600 mg acetylcysteine effervescent tablet contains about 140 mg sodium (corresponding to about 350 mg Na+ for these cases, it is suggested to use Fluimucil granulate or syrup ready for the use or other salt-free acetylcysteine preparation.

**Pregnancy/Lactation**

Pregnancy category B.

FLuimucil must be administered only under strict medical control during the pregnancy period.

No studies concerning the passage of N-acetylcysteine into the mother’s milk are available. Therefore, by considering both the possible risks of adverse reactions in suckling and the therapeutic benefits of lactation, all mothers under therapy with FLuimucil should discontinue lactation.

**Adverse events**

Sometimes mild gastrointestinal disturbance such as pyrosis, nausea, vomiting or diarrhoea are reported. In predisposed patients, hypersensitivity reactions affecting skin and respiratory organs may appear. The patient’s breath could have an unpleasant odour, probably due to the division of sulphur hydrogen.

**Interactions**

Owing to N-Acetylcysteine reactive thiol group, the effect of ampicillin, tetracycline macrolides, cephalosporins, aminoglycoside and amphotericin could be decreased in case direct N-acetylcysteine contact with these substances (aerosol solutions, perfusions, etc.). As for amoxicillin, it must be noted that concomitant administration of N-Acetylcysteine and this antibiotic is suggested to space out the administration by at least a 2-hour interval.

In case of concomitant administration of glyceryl nitrate, the relevant vasodilating and thomocyte aggregation inhibiting effect could be increased.

Concomitant antitussive administration: see "Use restrictions".

**Over dosage**

No N-acetylcysteine overdosage was reported so far.

**Special warnings**

Storage

Fluimucil is to be stored away from light at humidity. Keep the product away from the reach of children. The medicine must not be used beyond the expiry date printed on the product packaging, which is indicated with the abbreviation “EXP”.

Once opened, the syrup ready for the use should be stored for 15 days at room temperature (15-25°C).

**Incompatibilities**

N-acetylcysteine is incompatible with most metals, and is inactivated by oxidizing substances.

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