Fluimucil®

Composition
Active ingredient: acetylcysteine.

Excipients
Granule sachets: flavours, aspartame, sorbitol.
Effervescent tablets: flavours, aspartame.
Syrup ready for the use: flavours, saccharin, preservatives: E 218, E 211.
Film-coated tablets: Excipients q.s. for each tablet.

Galenic formulation and amount of active ingredient for each pharmaceutical form
Granule sachets containing 100, 200 and 600 mg acetylcysteine.
Effervescent tablets containing 200 and 600 mg acetylcysteine.
Syrup ready for the use containing 100 mg acetylcysteine / 5 ml.
Film-coated tablets containing 600 mg acetylcysteine.

Indications/Therapeutic use
The product is indicated in all respiratory tract diseases leading to the formation of dense secretions, difficult to be expectorated, such as acute and chronic bronchitis, laryngitis, sinusitis, tracheitis, flu, bronchial asthma and (as additional treatment) mucoviscidosis.

Posology/Method of administration
Usual posology for acute diseases
Children from 2 to 12 years of age: One 100 mg sachet or 5 ml syrup ready for the use 3 times daily or 200 mg twice daily.
Children beyond 12 years of age and adults: 600 mg daily, divided into one or more administrations (e.g. 200 mg or 10 ml syrup ready for the use 3 times daily).
Special posologies
Long-term treatment: 400–600 mg daily, divided into one or more administrations, with a maximum therapy duration of 3-6 months.
If mucus production and the consequent cough do not disappear after two weeks of treatment, it is necessary to consult a physician, who has to find out the cause of such persistence, in order to exclude a possible malignant disease of the respiratory tract.
Mucoviscidosis: as above, but also for children as from 6 years of age, 200 mg or 10 ml syrup ready for the use 3 times daily or 600 mg once daily.
Dissolve the content of one sachet or one effervescent tablet into a glass of cold or warm water. It is recommended not to mix Fluimucil concomitantly with other medicines.
The slight sulfur odour upon sachet or blister opening promptly evaporates and does not affect in any way the product efficacy.

Contraindications
Infants aged under 2 years.
Ascertained hypersensitivity to acetylcysteine or to any of the product excipients;
active peptic ulcer;
phenylketonuria (granule sachets, effervescent tablets, due to the presence of aspartame as excipient, which is metabolized to phenylalanine);
intolerance to fructose, e.g. in case of hereditary fructose-1,6-diphosphatase deficiency (due to the presence of the sweetening agent sorbitol, which is metabolized to fructose);
syrup ready for the use: ascertained hypersensitivity to: E 211, E 218, cross-allergies.

Special warnings and precautions for use
Relative contraindications
600 mg effervescent tablets and film-coated tablets: children below 12 years of age (in children suffering from mucoviscidosis: below 6 years of age).
The concomitant administration of an antitussive is not medically appropriate (see below «Special warnings and precautions for use»).
Special warnings and precautions for use
Caution is required in case of patients with risk of gastrointestinal bleeding (e.g suffering from latent peptic ulcer or oesophageal varices), as some data indicate that orally administered acetylcysteine may precipitate vomiting.
Caution is required also in patients suffering from bronchial asthma or with a hyperreactive bronchial system owing to the risk of bronchospasm.
In case of onset of hypersensitive reactions or bronchospasm, the treatment should be immediately discontinued and, if necessary, appropriate therapeutic measures should be applied.
The concomitant administration of an antitussive, by suppressing the cough reflex and the physiological self-cleaning mechanism of respiratory airways, may cause a mucus accumulation, with consequent risk of bronchospasm and respiratory tract infections (see «Relative contraindications»).
Hypertensive subjects and subjects on strict salt-free regimens, should be warned about the presence of 140 mg sodium (corresponding to about 350 mg NaCl) in each 200 mg and 600 mg acetylcysteine effervescent tablets. In these cases, it is recommended to use Fluimucil granule sachets, lingual or syrup ready for the use or other salt-free acetylcysteine preparations.

Interaction with other medicinal products and other forms of interaction
Owing to acetylcysteine reactive radical thiol group, the effect of ampicillin, tetracyclines, macrolides, cephalosporins, aminoglycosides and amphotericin may be decreased in case of direct acetylcysteine contact with these substances (solutions for aerosol, perfusions, etc.). The concomitant use of acetylcysteine increases amoxicillin tissular levels. Therefore, in case of concurrent oral use of acetylcysteine and antibiotics, the administrations should be spaced out by at least a 2-hour interval.
The concomitant administration of glycerol nitrate, may increase the vasodilating as well as the thrombocyte aggregation inhibiting effect.
Concomitant administration of an antitussive: see «Special warnings and precautions for use».

Pregnancy/Lactation
Pregnancy
The available data relating to a limited number of exposed pregnancies evidence no undesirable effects on pregnancy evolution or foetus or newborn safety. No epidemiologic studies are available. Studies in animals revealed no direct or indirect toxicity affecting pregnancy and embryonal, foetal and/or postnatal development.
Anyway, due caution is recommended when using the product during pregnancy.
Lactation
No studies concerning acetylcysteine excretion into the mother's milk are available. Anyway, due to the unclear risk of undesirable effects on the suckling and by considering the therapeutic benefit for breastfeeding women, as precautionary measure lactation should be discontinued during Fluimucil administration.

Effects on ability to drive and use machines
None known so far.

Undesirable effects
Rarely mild gastrointestinal disorders such as pyrosis, nausea, vomiting or diarrhoea and, in very rare cases, urticaria, headache and fever have been reported. Hypersensitivity reactions, affecting skin or respiratory organs may appear in predisposed patients; bronchospasm may also occur (see «Special warnings and precautions for use») in patients suffering from bronchial asthma and with a hyperreactive bronchial system.
The patient's breath may have an unpleasant odour, possibly due to sulfur hydrogen division.

Overdose
To date, no cases of overdose are known.

Shelf-life
Do not use the product after the expiry date which is reported on the carton after the abbreviation «EXP».
Once opened, the syrup ready for the use can be stored for 15 days at room temperature (15–25°C).

Special precautions for storage
Store below 25°C.

This leaflet was revised in October 2010

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