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Fluimucil® A 600 Effervescent Tablet 600mg

Fluimucil® Granules 600mg/sachet

For oral use

CHARACTERISTICS
Acetylcysteine (NAC), the active ingredient of FLUIMUCIL® A Effervescent Tablet 600mg and Fluimucil® Granules 600mg, exerts an intense mucolytic action on mucous and mucopurulent secretions, by depolymerizing the mucoproteic complexes and the nucleic acids which confer viscosity to the vitreous and purulent component of the sputum and of other secretions. Furthermore, NAC, exerts a direct antioxidant action, being provided with a free thiol (-SH nucleophilic) group, which is able to interact directly with the electrophilic groups of the oxidant radicals. Of particular interest is the recent demonstration that NAC protects the ∝-1-antitrypsin, enzyme inhibitor of elastase, from the inactivation due to the action of hypochlorous acid (HOCl), a powerful oxidant agent produced by the myeloperoxidase enzyme of activated phagocytes. These features make FLUIMUCIL® A Effervescent Tablet 600mg and Fluimucil® Granules 600mg particularly suitable for the treatment of acute and chronic affections of the respiratory system, characterized by thick and viscous mucous and mucopurulent secretions. Furthermore, the molecular structure permits the molecule to cross easily cellular membranes. Inside the cell, NAC is deacetylized, forming L-cysteine, an amino acid indispensable for the glutathione synthesis (GSH). GSH is a highly reactive tripeptide, found ubiquitously in the various tissues of animals and is essential for the maintenance of functional capacity as well as cellular morphological integrity, as it represents the most important protective, endocellular mechanism against oxidant radicals, either of external or internal nature. As well as towards numerous cytotoxic substances. NAC plays a role of primary importance in the maintenance of adequate GSH levels thus contributing to the cellular protections from harmful agents which, through progressive GSH depletion, would be able to express their cytotoxic actions, as in the case of acetaminophen poisoning. Due to this mechanism of action, NAC is also indicated as a specific antidote in acetaminophen poisoning. In the course of a cyclophosphamide treatment and in haemorrhagic cystitis, (in the latter case it provides SH-groups necessary to inactivate acrolein, a toxic metabolite that affects the urinary mucosa, whilst not interferring with chemotherapy).

INDICATIONS
FLUIMUCIL® A Effervescent Tablet 600mg and Fluimucil® Granules 600mg are indicated as an adjuvant treatment in certain clinical condition characterizedby the presence of thick and viscous mucoid or mucopurulent secretions such as:
- Chronic bronchopulmonary diseases (chronic obstructive pulmonary disease, emphysema with bronchitis, chronic asthmatic bronchitis, bronchiectasis);
- Acute bronchopulmonary diseases (asthma with bronchial mucus plugging, bronchitis, bronchopneumonia, tracheobronchitis, bronchiolitis, pulmonary complications of cystic fibrosis, pulmonary complications associated with surgery).

CONTRAINDICATIONS
- Known hypersensitivity to acetylcysteine or to any excipients.
- Children under 2 years of age.
- FLUIMUCIL® A Effervescent Tablet 600mg and FLUIMUCIL® Granules 600mg contains aspartame, thus it is contraindicated in patients suffering from phenylketonuria.

POSOLOGY
Adults and children above 6 years
- 1 tablet of FLUIMUCIL® A Effervescent Tablet 600 mg a day (preferably in the evening).
- 1 sachet of FLUIMUCIL® Granules 600mg a day (preferably in the evening)

The duration of treatment should be 5 to 10 days in the acute treatment, whereas it may be continued in the chronic states for several months, according to the advice of the physician.

MODALITY OF USE
Dissolve the tablets or the contents of the sachets in a glass containing a small quantity of water, mixing it, if necessary, with a spoon. A palatable solution is thus obtained, which can be drunk directly from the glass.

WARNING AND PRECAUTIONS
Caution should be taken in patients suffering from or with a history of peptic ulcer especially in case of concomitant administration of other medicines with a known irritating effect on the gastric mucosa.
Patients suffering from bronchial asthma must be strictly controlled during the therapy; should bronchospasm occur, the treatment must immediately be suspended.
The administration of acetylcysteine, mainly at treatment start, might fluidify bronchial secretion and increase their volume. If the patient is not able to effectively expectorate, postural drainage and bronchoaspiration should be performed.
Acetylcysteine may moderately affect histamine metabolism, therefore caution should be used when administering the product for long-term therapy in patients with histamine intolerance, since symptoms of intolerance can occur (headache, vasomotor rhinitis, itching).
The possible presence of a sulphureous odour does not indicate an alteration of the product but is a characteristic of the active ingredient contained in this preparation.
As Fluimucil® A Effervescent Tablet 600mg contains sodium (156.9mg per dose) this has to be taken into consideration by patients on a controlled sodium diet.
FLUIMUCIL Granules® 600mg contains sorbitol if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

INTERACTION
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Drug-drug interaction
Interaction studies have only been performed in adults.
Antitussive drugs and mucolytic agents, like acetylcysteine, should not be concurrently administered, because the reduction in cough reflex could lead to accumulation of bronchial secretions.
Activated charcoal may reduce the effect of acetylcysteine.
Dissolution of acetylcysteine formulations concomitantly with other drugs is not recommended.
Reports of an inactivation of antibiotics resulting from acetylcysteine so far only relate to in-vitro tests in which the relevant substances were mixed directly. Nevertheless, when other oral drugs or antibiotics are required, it is advisable to administer them 2 hours apart from acetylcysteine. This does not relate to loracarbef.
Concurrent administration of nitroglycerin and acetylcysteine has been shown to cause significant hypotension and enhance temporal artery dilation. If concurrent nitroglycerin and acetylcysteine therapy is necessary, patients should be monitored for hypotension, which can be severe, and warned of the possibility of headaches.

Concurrent use of acetylcysteine and carbamazepine may result in subtherapeutic carbamazepine levels.

Drug-Lab modifications
Acetylcysteine may cause interference with colorimetric assay method for salicylate measurement.
Acetylcysteine may interfere with urine ketone test.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy
There are limited clinical data from the use of acetylcysteine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of FLUIMUCIL® A Effervescent Tablet 600mg and FLUIMUCIL® Granules 600mg during pregnancy. Prior to use in pregnancy, the potential risks should be balanced against the potential benefits.

Lactation
It is unknown whether acetylcysteine/metabolites are excreted in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from FLUIMUCIL® A Effervescent Tablet 600mg and FLUIMUCIL® Granules 600mg therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
No data are available on the effect of acetylcysteine on human fertility. Animal studies do not indicate harmful effects with respect to fertility for humans at the recommended doses.
If you are pregnant or brestfeeding, ask your doctor or pharmacist for the advice before taking this medicine.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Acetylcysteine has no known influence on the ability to drive and use machines.

OVERDOSE
There is no specific antidote for acetylcysteine and treatment is symptomatic.
If you take more Fluimucil® A Effervescent Tablet 600mg or FLUIMUCIL Granules® 600mg than you should, you might experience nausea, vomit or diarrhoea. Contact your doctor.

SIDE EFFECTS
The most frequent adverse events associated with the oral administration of acetylcysteine are gastrointestinal in nature. Hypersensitivity reactions including anaphylactic shock, anaphylactic/anaphylactoid reaction, bronchospasm, angioedema, rash and pruritus have been reported less frequently.
In the table below adverse reactions are listed by system organ class and frequency (very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data).
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System-organ class	Undesirable effects			
	Uncommon (>1/1,000; <1/100)	**Rare** (>1/10,000; <1/1,000)	**Very rare** (<1/10,000)	**Not known**
Immune system disorders	Hypersensitivity		Anaphylactic shock, anaphylactic/ anaphylactoid reaction	
Nervous system disorders	Headache			
Ear and labyrinth disorders	Tinnitus			
Cardiac disorders	Tachycardia			
Vascular disorders			Haemorrhage	
Respiratory, thoracic and mediastinal disorders		Bronchospasm, dyspnoea		
Gastrointestinal disorders	Vomiting, diarrhoea, stomatitis, abdominal pain, nausea	Dyspepsia		
Skin and subcutaneous tissue disorders	Urticaria, rash, angioedema, itching			
General disorders and administration site conditions	Fever			Face oedema
Investigations	Reduced arterial pressure			

In very rare cases, the occurrence of severe skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome has been reported in temporal connection with the administration of acetylcysteine. In most cases at least one co-suspect drug more probably involved in triggering the reported mucocutaneous syndrome could be identified. Because of this, medical advice should be sought straight away if any new changes to the skin or mucous membranes occur, and acetylcysteine should be stopped immediately. A decrease in platelet aggregation in the presence of acetylcysteine has been confirmed by various investigations. The clinical significance has not yet been established. If you get any side effects, talk to your doctor or pharmacist.

PACKAGING
- FLUIMUCIL® A Effervescent Tablet 600mg - 10 or 30 effervescent tablets of 600mg acetylcysteine.
- FLUIMUCIL Granules® 600mg - 20 sachets of 600mg acetylcysteine

Do not store above 30°C, protect from heat and humidity

KEEP OUT OF SIGHT AND REACH OF CHILDREN

MANUFACTURED BY
Zambon Switzerland Ltd.
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