Fluimucil 600mg
Effervescent tablets
N-acetylcysteine

Pharmacotherapeutic category
mucolytic
Antidote

Therapeutic indications
Respiratory characterizes treatment of diseases as hypersecretion thick and sticky: acute bronchitis, chronic bronchitis and its exacerbations, pulmonary emphysema, cystic fibrosis and bronchiectasis.
Antidotic treatment
Accidental or deliberate poisoning by paracetamol.
Uropathy by ISO and cyclophosphamide.

Contraindications
Hypersensitivity to the active substance or to any of the excipients.
Generally contraindicated in pregnancy and lactation (see Warnings).

Precautions for use
Patients with asthma should be monitored closely during therapy, if it appears bronchospasm, treatment must be discontinued immediately.
It requires special attention the use of the medicine in patients with peptic ulcer or a history of peptic ulcer, especially in case of simultaneous intake of other drugs with a known gastrolesivo effect.

Interactions
Inform your doctor or pharmacist if you have recently taken any other medicines, including medicines obtained without a prescription.
Drug-drug
Were conducted drug-drug interaction studies have only on adult patients. Antitussives medicines and N-acetylcysteine must not be taken simultaneously as the decrease of the cough reflex may lead to an accumulation of bronchial secretions.
Activated charcoal may reduce the effect of N-acetylcysteine.
It is advisable not to mix other drugs with the Fluimucil solution.
The information available about the interaction antibiotic-N-acetylcysteine are based on in vitro tests, in which the two substances, which showed a decreased activity of the antibiotic were mixed. However, as a precaution, it is recommended to take oral antibiotics for at least two hours after the administration of N-acetylcysteine. It has been shown that the simultaneous administration of nitroglycerin and N-acetylcysteine cause significant hypotension and determines temporal artery dilation with possible onset of headache.
If you require co-administration of nitroglycerin and N-acetylcysteine, it is necessary to monitor patients for the appearance of hypotension may be severe and alert them about the possible onset of headache.
Drug-lab test
The N-acetylcysteine can cause interference with the assay method for the colorimetric determination of salicylates.
The N-acetylcysteine can interfere with the test for the determination of urine ketone.

Special warnings
The possible presence of a sulfurous odor does not indicate alteration of the preparation but is own of the active substance contained in it.
The administration of N-acetylcysteine, especially early in treatment, can thin bronchial secretions and increase at the same time the volume. If the patient is unable to expectorate effectively, to avoid the retention of secreted necessary to resort to postural drainage and tracheal suction.

Pregnancy and breastfeeding
Ask your doctor or pharmacist before taking any medicine. Although Fluimucil Teratology studies with animals have shown no teratogenic effect, however, as with other drugs, its administration during pregnancy and during the lactation period, must be carried out only if clearly needed under the direct control doctor.

Effects on ability to drive and use machines
There are assumptions or evidence that the drug would affect attentional skills and reaction times.

Important information about some of the ingredients
The tablets contain 156.9 mg of sodium per dose: keep in mind that information in the case of patients with impaired renal function or patients on a controlled sodium diet.
The tablets contain a source of phenylalanine which may be harmful for patients with phenylketonuria.

Dose, method and time of administration
Treatment of respiratory disorders
1 tablet per day (preferably in the evening). Any dosing adjustments may relate la frequency of administration or dose fractionation but they must be within the maximum daily dose of 600 mg. The duration of therapy is 5 to 10 days in acute and chronic forms will be continued, in the opinion of the doctor, for periods of several months.

Accidental or deliberate poisoning by paracetamol
Orally, initial dose, 140 mg / kg of body weight to be administered as soon as possible, within 10 hours after the toxic agent, followed every 4 hours, and for 1-3 days to single doses of 70 mg / kg of weight.

Uropathy to use and cyclophosphamide
In a typical cycle of chemotherapy with cyclophosphamide and iso of 1.200 mg / ml of body surface area per day for 5 days every 28 days, the N-acetyl-cysteine may be administered orally at a dose of 4 g / day on the days of chemotherapy treatment distributed in 4 doses of 1 g.

How to use
Dissolve one tablet in a glass containing a little 'of water. stirring as needed with a spoon.
To facilitate the escape of the compressed it is recommended the opening of the blister pack to tear, using the side notches.

Overdose
Overdose can cause gastrointestinal symptoms such as nausea, vomiting and diarrhea. If accidentally swallowed / taken an overdose of Fluimucil immediately notify your doctor or contact the nearest hospital. If you have any further questions on the use of Fluimucil, please consult your doctor or pharmacist.

Side effects
Inform your doctor or pharmacist if you have recently taken any other medicines, including medicines obtained without a prescription.

System Organ Class Adverse Reactions
uncommon
(> / = 1 / 1,000, <1/100) Rare
(> / 0 = 1 / 10,000, <1 / 1,000) Very rare (<1 / 10,000) Not known
Immune system disorders Hypersensitivity Anaphylactic shock, anaphylactic / anaphylactoid
Nervous system disorders Headache
Ear and labyrinth Tinnitus
Cardiac disorders Tachycardia
Vascular disorders Hemorrhage
Respiratory, thoracic and mediastinal disorders Bronchospasm, dyspnoea bronchial obstruction
Gastrointestinal disorders Vomiting, diarrhea, stomatitis, abdominal pain, nausea, dyspepsia
Skin and subcutaneous tissue disorders Urticaria, rash, angioedema, pruritus
In very rare cases, there was the appearance of serious skin reactions in temporal connection with the intake of N-acetylcysteine, such as Stevens-Johnson syndrome and Lyell's syndrome. Although in most cases has been identified at least one other suspected drug most probably involved in the genesis of these mucocutaneous syndromes, in case of mucocutaneous disorders should consult your doctor and taking N-acetylcysteine should be stopped immediately.

Some studies have confirmed a reduction of platelet aggregation while taking N-acetylcysteine. Its clinical significance of these findings has not yet been defined. Compliance with the instructions given in this leaflet reduces the risk of side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Shelf life and storage
Deadline: See expiry date on the package. The expiry date refers to the sealed container when stored. Caution: Do not use the medicine after the expiration date on the package. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

KEEP THE MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN

Composition
Fluimucil 600 mg effervescent tablets
Each tablet contains
Active ingredient: N-acetylcysteine 600 mg
Excipients: Sodium bicarbonate; anhydrous citric acid; Lemon flavoring; aspartame

Pharmaceutical form and contents
effervescent tablets.
Box of 30 tablets of 600 mg