Fluimucil 300mg / 3ml
Solution for injection, nebulizer, for instillation endotracheopulmonary
N-acetylcysteine

Pharmacotherapeutic category
Fluidizing mucolytic.
Antidote as antioxidant or a precursor of glutathione.

Therapeutic indications
Treatment of respiratory disorders characterized by hyper-dense 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.
Children under the age of 2 years, except antidotico treatment.

Precautions for use
Mucolytics can induce bronchial obstruction in children less than 2 years. In fact, the ability of the bronchial mucus drainage is limited in this age group, because of the physiological characteristics of the respiratory tract.
They should therefore not be used in children under 2 years of age (see section "Contraindications").
The administration of antidotiche doses in patients with less than 40 kg body weight should be done under strict medical supervision as there is the possible risk of excessive administration of fluids resulting in hyponatremia, seizures and death. It is still recommended to read carefully the information in the section "Dosage, method and timing of administration".
Patients with gill asthma should be monitored closely during therapy: if it appears bronchospasm its 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. The administration of N-acetylcysteine, especially by aerosol, at the beginning of treatment, can fluidize bronchial secretions and increase at the same time the volume; if the patient is unable to expectorate effectively, to avoid the retention of secretions is necessary to resort to postural drainage or, possibly, to the tracheal suction. The administration of N-acetylcysteine by intravenous route requires the supervision of a doctor. The occurrence of side effects, following administration of N-acetylcysteine in intravenous perfusion, is more likely if the drug is administered rapidly or in excessive amounts. And therefore it recommended strictly follow the information in the section "Dosage, method and timing of administration".
The intake of N-acetylcysteine in antidotici doses may prolong the "prothrombin time" (index reduced prothrombin, increased INR).

Interactions
Inform your doctor or pharmacist if you have recently taken any other medicines, including medicines obtained without a prescription.
Drug-drug
In case of treatment with nitroglycerine medications should consult your doctor. The concomitant use of nitroglycerin and N-acetylcysteine because in fact significant hypotension and determines temporal artery dilation, which may cause headache; it is therefore necessary to monitor the pressure. 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.
Inhalants and Endotracheopulmonary the Fluimucil can be administered together with common bronchodilators, vasoconstrictors, etc. In this case, the product should be used as soon as possible. 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 advisable not to mix antibiotics to N-acetylcysteine solution.

Drug lab test
The N-acetylcysteine can cause interference with the assay for the determination of the salicylates and for the determination of urine ketone.

Special warnings
The Fluimucil presents, opening the vial, a sulfurous odor which, however, does not disturb in any way the administration of the preparation. The solution of N-acetylcysteine in the open ampoule or transferred to the device for aerosols, may exceptionally assume a pink coloring, without that for this the activity and tolerability of the preparation are compromised.

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 should be carried out only if clearly needed under the direct control of the doctor.

Effects on ability to drive and use machines
There is no evidence that the drug would affect the ability to drive or operate machinery.

Important information about some of the ingredients
A Fluimucil vial contains 43 mg (1.9 mmol) of sodium: keep in mind that information in the case of patients with impaired renal function or patients on a controlled sodium diet.

Dose, method and time of administration
intravenous administration (from paracetamol intoxication): initial dose of 150 mg / kg of body weight added to an equal volume of 5% glucose solution and intravenously injected in 15 minutes.
Subsequent doses: 50 mg / kg administered in 4 hours by infusion with glucose solution 5% followed by a further dose of 100 mg / kg by perfusing by venipuncture in 16 hours, always with glucose 5% solution.
aerosol administration: spray container for a vial each session, doing 1-2 sessions per day for 5-10 days.
Given the high tolerability of the preparation, the frequency of sessions and doses for each of them can be modified by the physician within fairly wide limits, in relation to the clinical form and to the therapeutic effect, and without the need to clearly differentiate the doses for the ‘adult to pediatric.
Instillazione endobronchial: administering, with the chosen mode (permanent catheters, bronchoscopy, etc.), 1 vial per time 1-2 times a day or in relation to the needs.
Instillations or washings ITE or other cavities: the average dose is 1 / 2-1 ampoule time.

Overdose
intravenously
symptoms
The overdose symptoms are similar but more severe than those mentioned in section 'Undesirable effects'.
Treatment
The overdose therapy is based on the immediate suspension of the infusion, a symptomatic treatment and resuscitation procedures. There are no specific treatments antidotici; the NAC is dializzatile.

Inhalation use and Endotracheopulmonary
There were no cases of overdose in patients receiving inhaled or Endotracheopulmonary.
excessive doses of inhaled or Endotracheopulmonary could however lead to excessive fluid and secretions so massive, especially in patients with sputum production and cough reflex deficit and depressed, you may need to resort to instrumental methods of bronchoscopy.
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, contact your doctor or pharmacist.
Side effects
Like all Fluimucil medicines can cause side effects, although not everybody gets them.
Inhalation use or Endotracheopulmonary:
Hypersensitivity, bronchospasmo, rhinorrhea, gill obstruction, stomatitis, vomiting, nausea, urticaria, rash (rash), pruritus.
Parenteral:
Anaphylactic shock, anaphylactic reactions, anaphylactoid reactions, hypersensitivity, tachycardia, bronchospasm, dyspnea, vomiting, nausea, angioedema, urticaria, flushing, rash (rash), pruritus, facial edema, decreased blood pressure, prolonged prothrombin time.
In very rare cases, there was the appearance of serious adverse reactions affecting the skin such as Stevens-Johnson syndrome and Lyell's syndrome related to the assumption of N-acetylcysteine.
If you experience signs of mucocutaneous alterations you should contact your doctor immediately and taking N-acetylcysteine should be stopped immediately.
The patient is asked to tell your doctor or pharmacist any side effects not listed in this leaflet.
Compliance with the instructions contained in the explanatory 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. 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 EXPIRY DATE INDICATED ON THE PACKAGING
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
Storage: it is advisable to open the vials of Fluimucil ready to use: open vials can be used only when stored in the refrigerator for a maximum of 24 hours. The preserved opened vials should not be used for injection. Where the N-acetylcysteine solution was mixed with that of a bronchodilator of other medication, it must be used in the shortest possible time and can not be preserved.

Composition
Each vial contains:
Active ingredient: N-acetylcysteine 300 mg.
Excipients: Sodium hydroxide, edetate disodium, water for injections.

Pharmaceutical form and contents
Vials: 5, 10 vials for injection, aerosol, instillation.