

FLUIMUCIL

300mg / 3ml

Solution for injection, nebulization,
endotracheobronchial instillation
N-Acetylcysteine

PHARMACOTHERAPEUTIC GROUP

Fluidifying, mucolytic agent.
Antidote as antioxidant and glutathione precursor.

THERAPEUTIC INDICATIONS

Treatment of respiratory tract diseases characterized by thick and viscous hypersecretion: acute bronchitis, chronic bronchitis and its exacerbations, pulmonary emphysema, mucoviscidosis and bronchiectasis.

Antidotal treatment

Accidental or voluntary acetaminophen poisoning.
Iso- and cyclophosphamide uropathy.

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients.
Children below 2 years of age, except for the antidotal treatment.

PRECAUTIONS FOR USE

Mucolytics may induce bronchial obstruction in children under 2 years of age. In fact, the capacity to clear bronchial mucus is limited in this age group, due to the physiological characteristics of the respiratory airways.

Therefore these medicines should not be used in children under 2 years of age (see section "Contraindications").

The administration of antidotal doses in patients with body weight lower than 40 Kg is to be performed under strict medical surveillance, due to the possible risk of an excess overload of liquids, with consequent hyponatraemia, convulsions and death. It is however recommended to read carefully the indications reported under section "Dose, mode and time of administration".

Patients suffering from bronchial asthma should be carefully monitored during therapy; in case of bronchospasm onset, N-acetylcysteine administration should be immediately discontinued.

Special caution is required if the product is used in patients with peptic ulcer or history of peptic ulcer, especially in case of concomitant use of other medicines known to cause gastric injury.

N-acetylcysteine administration, especially by aerosol, at treatment initiation, can fluidify bronchial secretions, thus increasing concomitantly their volume; if the patient is unable to expectorate properly, postural drainage or, possibly, bronchoaspiration are required, to avoid secreta retention.

N-acetylcysteine administration by intravenous route requires medical supervision. Undesirable effects after administration of N-acetylcysteine by intravenous perfusion are more likely to occur if the injection is given too rapidly or with excessive doses. Therefore, it is recommended to strictly follow the indications reported under section 4.2 "Dose, mode and time of administration". N-acetylcysteine at antidotal doses may prolong prothrombin time (reduction in prothrombin index, increased INR).

INTERACTIONS

Please tell your doctor or pharmacist if you are taking or have recently taken any other

medicines, including medicines obtained without a prescription.

Drug-drug interaction

In case of treatment with nitroglycerin-based drugs, apply to your doctor. In fact, the concomitant administration of nitroglycerin and N-acetylcysteine induces a significant hypotension and causes the dilatation of the temporal artery, with possible onset of headache; therefore pressure monitoring is required.

Antitussive medicines and N-acetylcysteine should not be administered concomitantly, as cough reflex reduction may lead to an accumulation of bronchial secretions.

For inhalation and endotracheobronchial use, FLUIMUCIL may be administered concurrently with common bronchodilators, vasoconstrictors etc: in this case the product should be used as soon as possible.

The available information concerning antibiotic-N-acetylcysteine interaction refers to in vitro tests, that evidenced a decreased antibiotic activity after mixing the two substances. Anyway, as precautionary measure, it is suggested not to mix antibiotics with N-acetylcysteine solution.

Drug-laboratory test interactions

N-acetylcysteine may cause interferences with the colorimetric method for total salicylate assay and the determination of urinary ketones.

SPECIAL WARNINGS

Upon FLUIMUCIL ampoule opening, a sulfurous odour is emitted, which does not affect in any way the product administration. Acetylcysteine solution, stored in the opened ampoules or transferred into aerosol equipment, may exceptionally change to a light purple colour, without affecting the efficacy and tolerability of the preparation.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine. Although teratology studies carried out in animals with Flui mucil evidenced no teratogenic effects, as with other medicinal products, the administration during pregnancy and lactation should be performed only when strictly necessary and always under direct medical supervision.

Effects on ability to drive and use machines

There are no assumptions nor evidences that the drug may affect the ability to drive or use machines.

Important information about some of the ingredients

One Flui mucil ampoule contains 43 mg (1.9 mmol) of sodium; this should be taken into account in case of patients with reduced renal function or on low-sodium diets.

DOSE, MODE AND TIME OF ADMINISTRATION

Intravenous administration (in acetaminophen poisoning): Initial dose of 150 mg/kg body weight diluted with an equal volume of a 5% glucose solution and intravenously injected over 15 minutes. Subsequent doses: 50 mg/kg by intravenous

drip infusion over 4 hours followed by a further dose of 100 mg/kg by intravenous perfusion over 16 hours both in 5% glucose solution.

Aerosol administration: Nebulize one ampoule for each inhalation session, 1-2 times daily for 5-10 days.

Due to the high drug tolerability, frequency of administrations and relevant doses can be modified by the physician within rather wide-ranging limits, in response to the clinical condition and the therapeutic effect, without the need to markedly differentiate between doses for adults and for children.

Endobronchial instillation: Administer, according to the selected modalities (permanent tubes, bronchoscope, etc.) 1 ampoule at a time, 1-2 times daily or as need arises.

Instillations or endoauricular as well as other cavity washing: The average posology is ½ 1 ampoule each time.

OVERDOSE

Intravenous route

Symptoms

Overdose symptoms are similar in nature but more serious with respect to those indicated under section "Undesirable effects".

Treatment

Overdose therapy is based on the immediate discontinuation of the infusion, the adoption of a symptomatic treatment and resuscitation procedures. No specific antidotal treatments are available: NAC is dialyzable.

Inhalation and endotracheobronchial use

No cases of overdose have been observed in subject treated by inhalation or endotracheobronchial route.

Excess doses by inhalation or endotracheobronchial route could induce an excessive and massive fluidification of secretions, thus requiring, especially in subjects with deficient and depressed cough and expectoration reflex, the use of instrumental procedures of bronchoaspiration.

In case of accidental ingestion/intake of an excessive dose of FLUIMUCIL, inform immediately your doctor or apply to the nearest hospital.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Like all medicines, Flui mucil can cause side effects, although not everybody gets them.

Inhalation or endotracheobronchial use:

Hypersensitivity, bronchospasm, rhinorrhoea, bronchial obstruction, stomatitis, vomiting, nausea, urticaria, rash, itching.

Parenteral use:

Anaphylactic shock, anaphylactic reactions, anaphylactoid reactions, hypersensitivity, tachycardia, bronchospasm, dyspnoea, vomiting, nausea, angioedema, urticaria, flush, rash, itching, face oedema, decreased blood pressure, prolonged prothrombin time.

In very rare cases the onset of severe skin reactions, such as Stevens-Johnson syndrome and Lyell syndrome, was reported to be related with N-acetylcysteine administration.

If signs of mucocutaneous alterations appear, contact immediately your doctor and discontinue N-acetylcysteine administration.

The patient is requested to inform his/her doctor or pharmacist about any undesirable effects not listed in this leaflet.

The observance of the instructions contained in this package leaflet reduces the risk of undesirable 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.

EXPIRY DATE AND STORAGE

Expiry date: see the expiry date which is stated on the carton.

This date refers to the product in its original package and properly stored.

WARNING : DO NOT USE THIS MEDICINE AFTER THE EXPIRY DATE WHICH IS STATED ON THE CARTON

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Storage: It is recommended to open FLUIMUCIL ampoules at the moment of use: the opened ampoules are utilizable only if stored into a refrigerator for a time period not exceeding 24 hours. The stored opened ampoules cannot be re-used for injection. If N-acetylcysteine solution has been mixed with a bronchodilator or another drug solution, it should be used as soon as possible, and cannot be stored.

COMPOSITION

Each ampoule contains:

Active ingredient: N-acetylcysteine 300 mg.

Excipients: sodium hydroxide, sodium edetate, water for injections.

PHARMACEUTICAL FORM AND CONTENTS

Ampoules: 5, 10 ampoules for injection, aerosol, instillation.

MARKETING AUTHORIZATION HOLDER

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MANUFACTURER

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REVISION OF THE PACKAGE LEAFLET BY THE ITALIAN MEDICINES AGENCY

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