

富泌舒痰發泡錠600公絲

Fluimucil® A 600mg Effervescent Tablets

衛署藥輸字第023898號
本藥需由醫師處方使用

成份：Each Tablet Contains:

Acetylcysteine...600mg, Citric acid anhydrous...680mg, Sodium bicarbonate...500mg, Aspartame...20mg, Lemon flavour...100mg.

適應症：減少呼吸道黏膜分泌的黏稠性、蓄意或偶發之Acetaminophen中毒之解毒劑。

特性：乙醯半胱胺酸(Acetylcysteine, NAC)是Fluimucil®A的活性成份。它通過分解黏蛋白複合物、核酸，將膿性成份及其他分泌物從黏稠變為透明而發揮強烈溶黏液作用。

此外，NAC具有直接抗氧化作用，它提供一個能與親電子的氧化基團相互發生作用的自由硫氫基(親核的-SH)。特別有趣的是最近證實，NAC能阻止次氯酸(HOCl)對 α 1-抗胰蛋白酶(α 1-antitrypsin)和彈性蛋白酶(elastase)的破壞。次氯酸是一種強氧化劑，為活化吞噬細胞而產生的髓過氧化物酶(myeloperoxidase)。由於上述作用，使得Fluimucil®A對於急性和慢性的呼吸系統感染所引起濃稠性及化膿性分泌有極佳的功效。此外，NAC的分子結構能透過細胞膜，在細胞中分解成L-Cysteine (L-半胱胺酸)，此氨基酸是合成Glutathione(GSH)的主要成份。GSH是一種可高度再活化三肽，普遍存在於動物組織中，他提供細胞的保護機制，來保持細胞功能和細胞外型上的完整性。GSH代表最重要的保護功能，無論體內、體外，還是其他大多數之細胞毒素物質，其反應機制是抗氧化作用。

NAC在維持體內有足夠GSH之平衡中，扮演重要的角色。而GSH有助於保護細胞免受有毒物質藉著不斷消耗GSH，而產生細胞毒性作用，如Acetaminophen中毒時，NAC也可作為一種特殊的解毒劑。

用法用量：（六歲以上或成人）一次服用Fluimucil®A 600mg的發泡錠一片，一天一至二次(最好在晚上服用)。發泡錠置於玻璃容器中，加少量的水溶解，混勻，如果需要可藉助湯匙。這樣就獲得可口的溶液，可直接飲用。

禁忌：對本品內含成份過敏者，請勿投與。因本品含有甜味劑阿斯巴甜(Aspartame)，故苯酮尿患者不宜使用。

警告：在治療時，患有支氣管哮喘的病人用藥要嚴格控制。出現支氣管痙攣時治療必須立刻暫停。藥品可能有硫臭味，此並非表示產品變質，而是此製劑中含有活性成份的一種特徵。最好不要將其他藥物與Fluimucil®A的溶液混在一起。

副作用：本品口服，偶爾發生胃腸障礙如噁心和嘔吐，極少出現如皮疹和支氣管痙攣等過敏反應。

包裝：10片鋁箔盒裝。

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Fluimucil® A

For oral use



CHARACTERISTICS

Acetylcysteine (NAC), the active ingredient of Fluimucil® A, 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 α 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 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 deacetylated, 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 protection from harmful agents which, through progressive GSH depletion, would be able to express their cytotoxic action, 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 mucosae, whilst not interfering with chemotherapy).

INDICATIONS

Fluimucil® A is indicated as an adjuvant treatment in certain clinical condition characterized by 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, pul-

monary complications of cystic fibrosis, pulmonary complications associated with surgery).

CONTRAINDICATIONS

Known hypersensitivity to acetylcysteine.

Fluimucil® A contains aspartame, thus it is contraindicated in patients suffering from phenylketonuria.

POSODOLOGY

Adults (6 years old or above):

- 1 sachet Fluimucil® A 200 or 2 sachets Fluimucil® A 100, 3 times a day;
- 1 effervescent tablet of Fluimucil® A 600 mg a day (preferably in the evening).

For the prevention of an exacerbation, the use of Fluimucil® A (200 mg) sachets is recommended.

Children:

- 1 sachet of Fluimucil® A 100 from 2 to 4 times a day, according to the age.

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 as well as 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 or in the case of infants, be given with a tea spoon or in a feeding bottle.

WARNING AND PRECAUTIONS

Patients suffering from bronchial asthma must be strictly controlled during the therapy; should bronchospasm occur, the treatment must immediately be suspended.

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.

It is preferable not to mix other drugs with the Fluimucil® A solution.

ADVERSE EFFECTS

No unusual severe type of toxicity has been reported from the prescription experience of Fluimucil® A oral: slight gastrointestinal disturbances (nausea, dyspepsia, pyrosis) have occurred occasionally.

PACKAGING

- Fluimucil® A 600 - 10 or 30 effervescent tablets of 600 mg acetylcysteine.
- Fluimucil® A 200 - 30 sachets of 200 mg acetylcysteine.
- Fluimucil® A 100 - 30 sachets of 100 mg acetylcysteine.

KEEP OUT OF THE REACH OF CHILDREN

 **Zambon**