PACKAGE LEAFLET: INFORMATION FOR THE USER

FLUIMUKAN PLUS

600 mg effervescent tablets

Acetylcysteine

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1.WHAT FLUIMUKAN PLUS IS AND WHAT IT IS USED FOR

FLUIMUKAN PLUS is a medicine used to dissolve the thick and abundant secretion (mucus) in the airways.

FLUIMUKAN PLUS is used to dissolve secretions in acute and chronic diseases of the respiratory system and to facilitate expectoration in diseases of the respiratory system with abundant secretion.

2. BEFORE YOU TAKE FLUIMUKAN PLUS

Do not take FLUIMUKAN PLUS

• If you are allergic (hypersensitive) to Acetylcysteine, or any of the other ingredients of this medicine FLUIMUKAN PLUS should not be used in children younger than 14 years because of the high content of active substance. There are other pharmaceutical forms available for this population.

Take special care with FLUIMUKAN PLUS

• Severe skin reactions such as Stevens-Johnson syndrome (blisters on the mucous membranes of the mouth, throat, genitals and conjunctiva), or Lyell's syndrome (a severe skin disease with blistering) are rarely associated with the use of acetylcysteine. If there are any changes on the skin or mucous membranes, stop taking FLUIMUKAN PLUS and immediately contact your doctor.

• Caution is needed in patients who have or have had bronchial asthma or stomach or intestinal ulcers.

• Caution is needed in patients with intolerance to histamine. They need to avoid the long-term treatment, because FLUIMUKAN PLUS affects the metabolism of histamine and can lead to signs of intolerance, such as headache, acute rhinitis (inflammation of the nasal mucosa with formation of clear content) and itching.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Acetylcysteine / cough suppressants (medicines that stop the cough)
When combined with antitussives, it can cause serious suspension of secretion because of the prevention of the cough reflex. Because of this, the indications for this specific combined treatment should be considered carefully. So, before using these two medicines, you should ask your doctor.

Acetylcysteine / antibiotics (medicines for the treatment of inflammation)
Experimental studies have shown that acetylcysteine may decrease the effect of antibiotics (tetracycline, amninoglikozidi, penicillin). For safety reasons, antibiotics should be taken separately from FLUIMUKAN PLUS and after a time interval of at least 2 hours between the individual applications.
This does not apply to medicines whose active substances cefixime and loracarbef. They can be taken at the same time with acetylcysteine.

Pregnancy and breastfeeding

Pregnancy
Given that there is no enough experience with the use of acetylcysteine in pregnant women, the use of FLUIMUKAN PLUS is justified only if your doctor considers it absolutely necessary.
Breastfeeding
There are no data related to the excretion of acetylcysteine into the breast milk.
Therefore, FLUIMUKAN PLUS may be used during lactation only if your doctor considers it absolutely necessary.

Driving and using machines

Not implacable.

Important information about some of the ingredients of FLUIMUKAN PLUS

Each tablet contains 6.03 mmol (138.8 mg) of salt, which must be kept in mind in patients with restricted salt intake.
If your doctor ever said that you are hypersensitive to some sugars, talk to him or pharmacist before you start taking FLUIMUKAN PLUS.

Tablets FLUIMUKAN PLUS contain lactose. If your doctor told that you have intolerance to some sugars, consult your doctor before taking Fluimukan PLUS.

3. HOW TO TAKE FLUIMUKAN PLUS

Always take FLUIMUKAN PLUS exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

If you doctor did not prescribe otherwise, the usual dose is:
The following data can be used if your doctor did not prescribe Fluimukan PLUS in another regime. Please follow the instructions; otherwise Fluimukan PLUS cannot act properly.

Age	Total daily dose (effervescent tablets)
Adults and adolescents older than 14 years	One half of effervescent tablets twice a day or 1 effervescent tablet once daily (the equivalent of 600 mg of acetylcysteine per day)

Method of administration
Take Fluimukan PLUS after meal.
Effervescent tablets can be broken in half.
Please dissolve effervescent tablet in a glass of water and drink the entire content.

Duration of treatment
If your symptoms worsen or do not improve after 4-5 days, tell your doctor.
Please contact your doctor or pharmacist if you feel that the effect of Fluimukan PLUS is too strong or too weak.

If you take more FLUIMUKAN PLUS than you should
An overdose can cause irritation of the digestive system (nausea, vomiting, diarrhea and abdominal pain). Severe side effects or symptoms of poisoning with the excessive amount of acetylcysteine have not been reported. If you suspect you have taken too much FLUIMUKAN PLUS, you should immediately contact your doctor.

If you forget to take FLUIMUKAN PLUS
If you missed a dose, or if you did not take enough medicine, continue to take Fluimukan PLUS as described in the instructions for dosage.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (occurring in more than 1 in 10 patients); common (less than 1 in 10 patients); uncommon (less than 1 in 100 patients); rare (less than 1 in 1,000 patients) and very rare (less than 1 in 10,000 patients), including isolated reports.

General disorders and administration site conditions
Uncommon: headache, fever, allergic reactions (itching, hives, rash, difficulty breathing, rapid heartbeat, and low blood pressure)
Very rare: anaphylactic reactions progressing to shock.

Disorders of the respiratory system, thorax and mediastinum
Rare: respiratory distress (difficulty breathing), narrowing (spasm) of the airways, especially in patients with hyperactive asthma (obstructive airway disease, "sealing" or "shortness of breath")

Gastrointestinal disorders
Uncommon: inflammation of the lining of the mouth, abdominal pain, nausea, vomiting and diarrhea.

The occurrence of bleeding related to the application of acetylcysteine is very rarely reported, partly related to hypersensitivity reactions.

Countermeasures
At the first signs of hypersensitivity reaction (see above) Fluimukan PLUS should not be taken again. In this case, please contact your doctor.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE FLUIMUKAN PLUS

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date refers to last day of that month.
Shelf life: 3 years.

Store below 30 °C.

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.

6. FURTHER INFORMATION

What FLUIMUKAN PLUS contains

The active ingredient is acetylcysteine.
1 effervescent tablet contains 600 mg of acetylcysteine.

The other ingredients are:
Ascorbic acid (vitamin C) (E 300)
Citric acid, anhydrous (E 330)
Lactose, anhydrous
Mannitol (Ph.Eur.) (E421)
Sodium carbonate, anhydrous
Sodium citrate 2 H2O (E331)
sodium cyclamate
sodium hydrogen carbonate
Saccharin sodium 2 H2O
Zinc sulphate monohydrate
Aromatics (lemon).

Warning for diabetics
One effervescent tablet FLUIMUKAN PLUS contains 0.01 carbohydrate units.

What FLUIMUKAN PLUS looks like and contents of the pack
Fluimukan PLUS tablets are white, round, flat effervescent tablets with the division line. 10 effervescent tablets in an aluminum tube, in a box.

Supplier and Manufacturer

Regime of dispensing
The medicine is issued without doctor`s prescription.

MANUFACTURER
Lek farmacevtska družba dd, Verovškova 57, 1526 Ljubljana, Slovenia

MANUFACTURER OF THE MEDICINAL PRODUCT
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany