

FLUIMUKAN AKUT

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?

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

FLUIMUKAN AKUT 600 mg is a medicine used to dissolve the thick secretions (mucus) in the airways.

Therapeutic indication

Tablets FLUIMUKAN AKUT 600 mg are used to dissolve secretions in acute and chronic diseases of the respiratory system and to facilitate expectoration in diseases of the respiratory system with a thick secretion and reduced transport of mucus.

2. BEFORE YOU TAKE FLUIMUKAN AKUT

Do not take FLUIMUKAN AKUT

- If you are allergic (hypersensitive) to Acetylcysteine, or any of the other ingredients of this medicine FLUIMUKAN AKUT 600 mg 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 AKUT

- 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 AKUT 600 mg 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 AKUT 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.
- The use of FLUIMUKAN AKUT 600 mg, in particular at the start of treatment, may lead to softening of mucus (secretions from the bronchi / airways /), leading to the formation of increased amounts of mucus. If you are not able to cough up the generated amount, the doctor will recommend appropriate measures.

Taking other medicines

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

Studies concerning the interactions were carried out only in adult patients.

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 / active coal

The use of active coal may reduce the effects of acetylcysteine.

Acetylcysteine / antibiotics (medicines for the treatment of inflammation)

Experimental studies have shown that acetylcysteine may decrease the effect of antibiotics (tetracycline, aminoglikozidi, penicillin). For safety reasons, antibiotics should be taken separately from FLUIMUKAN AKUT 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.

Acetylcysteine / nitroglycerin

Simultaneous use of FLUIMUKAN AKUT may increase the dilation of blood vessels and enhance the effect of glyceryl trinitrate (nitroglycerin) on dilution of the blood. If a doctor considers that is necessary to simultaneously use these two drugs, the doctor will monitor and control the treatment because of the potential hypotension (blood pressure lowering) which can be serious and sometimes followed by headache.

Changes in laboratory parameters

Acetylcysteine may affect the analysis with salicylic content.

During urinalysis, acetylcysteine may affect the results of the analysis of ketone bodies.

Simultaneous dissolution of other medicines with acetylcysteine is not recommended.

Pregnancy and breastfeeding

Pregnancy

Given that there is no enough experience with the use of acetylcysteine in pregnant women, the use of Fluimukan akut 600 mg 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 akut 600 mg 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 AKUT

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 akut 600 mg.

Tablets Fluimukan akut 600 mg contain lactose.

Patients with rare hereditary diseases, such as hypersensitivity to galactose, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Each tablet contains 0.01 carbohydrate units, which should be kept in mind in patients with diabetes.

3. HOW TO TAKE FLUIMUKAN AKUT

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

Dose

Adults and young adults over the age of 14

1 effervescent tablet once a day

If you are suffering from cystic fibrosis:

Children aged 2-6 years:

100 mg of acetylcysteine in a suitable pharmaceutical form (syrup Fluimukan junior) four times a day.

Children and young adults over the age of 6 years:

600 mg of acetylcysteine 3 times daily in a suitable pharmaceutical form (Fluimukan akut 200 mg) three times a day.

Method of administration

The duration of treatment will be determined by the attending doctor that based on the nature and severity of the present medical condition.

In the presence of chronic bronchitis and cystic fibrosis treatment should last for a longer period of time to achieve protection against infection.

The duration of use of the medicine

Acetylcysteine should not be used for more than 4-5 days without medical supervision.

FLUIMUKAN AKUT is intended for oral administration. You should put the tablet in a glass full of water, wait until it is completely dissolved and drink the solution after a meal.

If you take more FLUIMUKAN AKUT 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 Fluijukan akut 600 mg, you should immediately contact your doctor.

If you forget to take FLUIMUKAN AKUT

If you forget to take a dose, take another as soon as you remember, unless it is almost time for your next dose. Remember to leave at least four hours between doses. Never double-up on a dose to make up for the one you have missed.

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.

Following side effects may occur:

Immune System

Uncommon: hypersensitivity reactions

Very rare: hypersensitivity reactions with the shock.

Nervous system

Uncommon: headache.

Ear and labyrinth disorders

Uncommon: ringing in the ears (tinnitus).

Cardiac disorders

Uncommon: rapid heart rate.

Disorders of the vascular system

Very rare: bleeding.

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: nausea, vomiting, diarrhea, abdominal pain, stomatitis (inflammation of the lining of the mouth)

Rare: heartburn (indigestion).

Skin and subcutaneous tissue disorders

Uncommon: Allergic reactions: bruising, itching, hives, an island on the skin and mucous membranes

General disorders and at the application site

Uncommon: increased body temperature

Unknown: swelling of the face.

Medical tests

Uncommon: low blood pressure.

Very rare, 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 the blistering) were reported to have occurred following the use of acetylcysteine. In most of the cases reported so far, at least one other medicine was also used, which increases described mucocutaneous reactions (on the skin and mucosa).

If you experience any new changes on the skin or mucosa, immediately contact your doctor and stop using Fluumukan akut 600 mg. Do not reuse Fluumukan akut 600 mg.

Various tests have confirmed that acetylcysteine reduces platelet aggregation. The clinical significance of this is still unclear.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUIMUKAN AKUT

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.

Store below 30 °C. Store in the original container to protect from moisture and light.

Do not use this medicine if you notice visible signs of deterioration.

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 AKUT contains

One effervescent tablet contains 600 mg of acetylcysteine.

Other ingredients:

- Ascorbic acid (vitamin C) (E 300)
- Citric acid anhydrous (E 330)
- lactose anhydrous
- Mannitol (Ph.Eur.) (E421)
- Sodium citrate dihydrate (E331)
- sodium hydrogen carbonate
- saccharin sodium
- sodium carbonate
- sodium cyclamate
- blackberry flavour

Warning for diabetics

One effervescent tablet Fluumukan akut 600 mg contains 0.01 carbohydrate units.

What FLUIMUKAN AKUT looks like and contents of the pack

Effervescent tablet

10 effervescent tablets in an aluminum tube, in a box

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Lek dd pharmaceutical company, Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany

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Last revision

October 2015