

FLUIMUKAN AKUT

100 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 100 mg is a medicine used to dissolve the thick secretions (mucus) in the airways. FLUIMUKAN AKUT 100 mg is used in respiratory diseases with abundant formation of thick mucus and difficult expectoration.

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

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 100 mg and immediately contact your doctor.

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

It is not recommended for use in patients with renal or liver failure, due to the additional input of nitrogenous substances.

Children

FLUIMUKAN AKUT 100 mg may be used in children younger than 2 years only with doctor's advice, because there is not enough experience with the use of this medicine in this age group.

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, 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.

Pregnancy and breastfeeding

Pregnancy

Given that there is no enough experience with the use of acetylcysteine in pregnant women, the use of Flumukan akut 100 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, Flumukan akut 100 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 3,5 mmol (80,5 mg) of salt, which must be kept in mind in patients with restricted salt intake.

Tablets Flumukan akut 100 mg contain lactose. If your doctor ever said that you are hypersensitive to some sugars, talk to him or pharmacist before you start taking Flumukan akut 100 mg.

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.

Age	Maximum daily dose (effervescent tablets)
Children from 2-5 years	1 effervescent tablet 2-3 times a day (a total of 200-300 mg acetylcysteine per day).
Children from 6-14 years	1 effervescent tablet 3-4 times a day (a total of 300-400 mg acetylcysteine per day).
Adults and children over 14 years	2 effervescent tablets 2-3 times a day (a total of 400-600 mg acetylcysteine per day).

Method of administration

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.

Duration of treatment

If the clinical picture does not improve after 4-5 days you should consult a doctor.

If you notice that the effect of Fluimukan acute 100 mg is too strong or perhaps not strong enough, inform your doctor.

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 Fluimukan akut 100 mg, you should immediately contact your doctor.

If you forget to take FLUIMUKAN AKUT

If you forget to take Fluimukan acute 100 mg or you take a lower dose than recommended continue taking the medicine according to the regular schedule.

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:

General disorders

Uncommon: Allergic reactions (itching, hives, rash, bronchospasm, angioedema, tachycardia and hypotension), headache, fever

Very rare: anaphylactic reactions including anaphylactic shock.

Respiratory system

Rare: dyspnea, bronchospasm - mainly in patients with bronchial asthma

Digestive system

Uncommon: stomatitis, abdominal pain, nausea, vomiting, diarrhea

There are very few reports of bleeding caused by acetylcysteine, as part of a hypersensitivity reaction.

If you notice some of the symptoms of hypersensitivity reactions, discontinue treatment with Flumukan AKUT 100 mg and immediately contact a doctor.
This includes any possible side effects not listed in this leaflet.

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. 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.

6. FURTHER INFORMATION

What FLUIMUKAN AKUT contains

The active ingredient is acetylcysteine
One effervescent tablet contains 100 mg of acetylcysteine.

Excipients: ascorbic acid (vitamin C), citric acid anhydrous, sodium cyclamate, sodium hydrogencarbonate, sodium carbonate, polyethylene glycol, sodium saccharin, forest fruit flavor, blackberries flavor.

What FLUIMUKAN AKUT looks like and contents of the pack

Flumukan AKUT 100 mg is available in the packing of 20 effervescent tablets.

Supplier and Manufacturer

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany
Lek dd pharmaceutical company, Verovškova 57, Ljubljana, Slovenia