

Package leaflet: Information for the patient

Fluimucil 600 mg effervescent tablets

Acetylcysteine

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.
- Ask your pharmacist if you need more information or advice .
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet

1. What Fluimucil is and what it is used for
2. What you need to know before you take Fluimucil
3. How to take Fluimucil
4. Possible side effects
5. How to store Fluimucil
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1. What Fluimucil is and what it is used for

Fluimucil 600mg effervescent tablets contains a medicine called acetylcysteine. Acetylcysteine breaks down and loosens thick mucus, making it runny and easy to cough up. Acetylcysteine is used in the treatment of airway diseases associated with an excess of mucus, especially acute bronchitis (inflammation of the air tubes of the lungs).

You must talk to a doctor if you do not feel better or if you feel worse after 5 days. Do not take the product for longer than 10 days without contacting your doctor. Fluimucil is intended for adults only.

2. What you need to know before you take Fluimucil

Do not take Fluimucil:

- if you are allergic to acetylcysteine or any of the other ingredients of this medicine (listed in section 6).
- if your child is under 2 years of age.
- if you are a child or a pregnant woman suffering with phenylketonuria.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluimucil

- If you have stomach ulcers or history of them.
- If you suffer from bronchial asthma, as you may need to be monitored closely whilst taking this medicine. If you experience difficulty in breathing, immediately stop taking Fluimucil and contact your doctor straight away.
- There are rare cases of severe allergic reactions associated with the use of Fluimucil: (high) fever, skin redness, joint pains and/or eye infection (Stevens-Johnson syndrome) or sudden allergic reactions accompanied by fever and blisters on the skin or peeling of the skin (Lyell

syndrome). If you notice any new changes in your skin or mucous membranes (e.g. throat, tongue or mouth lining), immediately stop taking Fluimucil and contact your doctor straight away.

- If you are unable to cough up fluid mucus effectively (e.g. elderly or frail patients with impaired cough reflex). Especially at the beginning of treatment, you need to take special care because the mucus secretion may increase in volume as it becomes more fluid.
- If you are allergic to histamine. Immediately contact your doctor if you develop symptoms of intolerance (headache, runny nose, itching) during therapy with Fluimucil.

On opening the packet, there may be a mild smell of sulphur (rotten eggs). This is a normal characteristic of this medicine and does not mean that it is not safe to use.

Children and adolescent

Do not give this medicine to children under 2 years of age because their ability to cough up may be limited (see section “Do not take Fluimucil”).

Acetylcysteine 600 mg effervescent tablets are not to be used by children between 2 and 18 years.

Other medicines and Fluimucil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as they may affect each other.

In particular:

- Cough-relieving medicines (antitussives), as they can cause a dangerous build-up of secretions.
- Activated charcoal (medicine used to treat traveller's diarrhoea), because it may reduce the effect of Fluimucil.
- Antibiotics, as some of them may be inactivated by Fluimucil. Oral antibiotics or other oral drugs should be taken separately from Fluimucil, and not within 2 hours.
- Nitroglycerin (medicine used to treat episodes of chest pain), as you may develop blood pressure decrease and headaches.
- Carbamazepine (medicine used to treat seizures and nerve pain), as its uptake may be reduced by Fluimucil.

Do not dissolve Fluimucil simultaneously with other drugs.

Effects of Fluimucil on laboratory tests

Fluimucil may affect the results of the tests for:

- measurement of salicylate,
- determination of ketone bodies in urine.

Pregnancy, breast-feeding and fertility

Pregnancy

There is a limited amount of data from the use of acetylcysteine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy or development of the child before, during or after birth. Only use Fluimucil, after careful consideration of the risks and benefits during pregnancy.

Breast-feeding

It is unknown whether acetylcysteine is excreted in breast milk. Only use Fluimucil, after careful consideration of the risks and benefits during breast-feeding.

Fertility

Based on available data, there are no indications for possible effects of the use of acetylcysteine on fertility.

Driving and using machines

There are no data available on the effect of acetylcysteine on the ability to drive or use machines. An effect is, however, not likely.

Fluimucil contains sodium bicarbonate

Fluimucil 600mg effervescent tablets contains 158 mg of sodium (main component of cooking/table salt) in each tablet.

This is equivalent to 7.9% of the recommended maximum daily dietary intake of sodium for an adult.

Fluimucil contains aspartame

Fluimucil 600mg effervescent tablets contains 20 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Fluimucil contains glucose (as a component of the lemon flavour)

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Fluimucil

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is:

1 effervescent tablet of Fluimucil taken once a day.

Dissolve one effervescent tablet into a small volume of water. Drink the solution immediately.

If your symptoms worsen or do not improve after 5 days from the treatment initiation, stop taking the product and contact your doctor.

Do not take the product for longer than 10 days without contacting your doctor.

It is recommended for elderly and for frail patients to take the effervescent tablet in the morning.

Use in children and adolescents

Fluimucil 600mg effervescent tablets must not be given to children under the age of 2 years.

Fluimucil 600mg effervescent tablets is not be used in children and adolescents up to 18 years.

Other forms of this medicine are more suitable in this group of patients.

If you take more Fluimucil than you should

If you take more Fluimucil than you should, you may develop problems related to stomach and intestines such as nausea, vomiting and diarrhoea. Contact your doctor immediately.

If you forget to take Fluimucil

If you forget to take an effervescent tablet, take your next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Very rare (may affect up to 1 in 10,000 people)

If you experience any of the following very serious side effects, stop taking Flumucil and contact your doctor or nearest hospital emergency department immediately:

- shock (strong decrease of blood pressure, paleness, restlessness, weak pulse, clammy skin, decreased consciousness) due to a sudden widening of blood vessels caused by severe allergy to certain substances (anaphylactic shock).
- Sudden fluid accumulation in the skin or mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and skin rash, often as an allergic reaction (angioedema).

If you have these reactions, it is possible that you have a serious allergic reaction to Flumucil. You need emergency medical care or need to be hospitalised.

- Bleeding (haemorrhages) is also a very rare side effect.

Rare (may affect up to 1 in 1,000 people)

- Difficulty in breathing (bronchospasm)
- Shortness of breath (dyspnoea)
- Upset stomach (dyspepsia)

Uncommon (may affect up to 1 in 100 people)

The following side effects have also been reported:

- Allergic reaction
This may manifest as bronchospasms and dyspnoea (see above), rapid heartbeat (tachycardia), itching (pruritus), skin rash with severe itching and formation of bumps (urticaria) and angio-oedema.
- Headache
- Ringing of the ears (tinnitus)
- Rapid heartbeat (tachycardia)
- Vomiting, diarrhoea
- Inflammation of the mouth (stomatitis)
- Stomach pain, nausea
- Hives (urticaria)
- Skin rash
- Swelling of the face, lips, throat or tongue (angioedema)
- Pruritus
- Fever (pyrexia)
- Lowered blood pressure

Unknown (frequency cannot be estimated from the available data)

- face edema (swelling of the face).
- platelet aggregation.

Various studies have shown that Flumucil may cause a decrease in platelet aggregation (aggregation of the blood components that leads the process of stop bleeding). The clinical significance of this effect is 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. You can also report side effects directly via Malta ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.

By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store Flumucil

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and on the carton. The expiry date refers to the last day of that month.

This medicine product does not require any special storage condition.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fluimucil 600mg effervescent tablets contains

The active substance is acetylcysteine. Each tablet contains 600 mg acetylcysteine. The other ingredients are: sodium hydrogen carbonate, citric acid anhydrous, aspartame (E951), lemon flavour (contains glucose, maltodextrin, arabic gum (E414), maize starch modified and ascorbic acid (E300)).

What Fluimucil 600mg effervescent tablets looks like and contents of the pack

Fluimucil 600mg effervescent tablets is white circular tablets. It is supplied in blisters containing 10 and 20 effervescent tablets. Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer

Zambon S.p.A.
Via Lillo del Duca 10
20091 Bresso (MI)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherland
Kinemucil acetylcysteine 600 mg bruistabletten

Malta
Fluimucil acetylcysteine 600mg effervescent tablets

Croatia
Respimucil Acetilcistein 600 mg šumeće tablete

Slovenia
Respimucil Acetilcistein 600 mg šumeče tablete

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Other sources of information

Detailed information on this medicine is available on the website of www.medicineauthority.gov.mt