

Package leaflet: Information for the patient

Fluimucil 200 mg granules for oral solution

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.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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
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1. What Fluimucil is and what it is used for

This medicine is called Fluimucil 200 mg granules for oral solution. Each sachet contains the active substance acetylcysteine. Acetylcysteine belongs to a group of medicines called mucolytics which work by thinning the mucus (phlegm) so that it can be coughed up more easily.

Fluimucil is used to treat:

- breathing difficulties caused by too much mucus in the lungs and airways or the mucus being too thick and sticky to cough up easily

2. What you need to know before you take Fluimucil

Do not take take Fluimucil:

- if you are allergic (hypersensitive) to acetylcysteine, other similar medicines (such as carbocysteine, erdoysteine or mecysteine), or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or, pharmacist or nurse before taking using Fluimucil

- if you suffer from asthma, as you may need to be monitored closely whilst taking this medicine
- if, before you start taking this medicine, you have a reduced ability or inability to cough, then it may be necessary to remove the mucus by suction after this medicine has loosened it
- if you have or have had a peptic ulcer, as Fluimucil may irritate your gastric wall. In particular if you use other drugs known to irritate the gastric wall
- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product
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- may cause allergic reactions

- when your doctor told you that you have an intolerance to histamine, since acetylcysteine may cause symptoms of intolerance (headache, vasomotor rhinitis, itching)
- if you are due to have any blood or urine tests, as acetylcysteine can interfere with some laboratory tests.

On opening the sachet, Fluimucil may smell of sulphur (rotten eggs). This is a normal characteristic of this medicine and does not mean that it is not safe to use. Upon addition of water the solution will have a citrus odour.

Children and adolescents

Do not use in children under the age of 2 years.

Other medicines and Fluimucil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines to treat coughs (e.g. cough syrup)
- activated charcoal, used to treat poisoning
- drugs used to treat bacterial infections, antibiotics. This medicine can prevent some antibiotics from working properly if they are taken at the same time as it. If you have been told this applies to you, you should take this medicine either two hours before or two hours after taking your antibiotics. If you are not sure if this applies to you, talk to your doctor or pharmacist.
- medicines to treat angina attacks, (tightness in your chest, neck and arm)
- carbamazepine, since acetylcysteine may decrease its effect

Fluimucil with food and, drink and alcohol

There are no special requirements to consider when taking this medicine with food, drink or alcohol.

Pregnancy and, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Fluimucil should not affect your ability to drive or operate machinery. If you experience side effects which may affect these abilities, do not drive or operate machinery until the effects have completely disappeared.

Fluimucil contains saccharin, orange flavour and granulate of orange juice sucrose

Each Fluimucil sachet contains the equivalent of 2.70 g sucrose. This should be taken into account when treating diabetic patients.

3. How to take Fluimucil

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Empty the sachet contents into a small amount of water in a glass and stir until it dissolves (mixes) completely, just before drinking. It is important to drink all of the mixture.

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

The recommended dose for adults and adolescents is 1 or 2 sachets 2 to 3 times a day, or as prescribed by your doctor depending on the condition.

The recommended dose for children is ½ of the sachet to 1 sachet up to 3 times a day depending on the condition.

If you take more Fluimucil than you should

If you accidentally take more Fluimucil than you have been prescribed, contact your doctor or get medical advice immediately. If possible, take the sachets, the box and this leaflet with you to show the doctor.

The following are all symptoms of an overdose:

- Feeling or being sick
- Diarrhoea

If you forget to take Fluimucil

If you forget to take a dose, take it as soon as possible. Take the next dose at the correct time, in accordance with the instructions given by your doctor. However, if it is almost time to take the next dose, do not take the dose you have missed; only take the next dose as normal.

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, Fluimucil can cause side effects, although not everybody gets them.

Stop taking Fluimucil and get medical advice straight away if you experience any of these very rare side effects (affecting less than 1 in 10,000 people):

- severe, life-threatening allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- severe bleeding (haemorrhaging)
- blistering, peeling, bleeding, scaling, or fluid filled patches on any part of your skin. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may have a serious skin problem.

Tell your doctor or pharmacist if any of the following side effects become serious or last longer than a few days:

Uncommon side effects (affecting less than 1 in 100 people)

- Headache
- A ringing sound in the ears (tinnitus)
- A fast heart rate
- Feeling or being sick
- Diarrhoea
- Inflammation of the skin in your mouth and on your lips
- Pain in your abdomen (tummy)
- An itchy raised rash
- Swelling of the deeper layers of skin, caused by a build up of fluid
- Itchy skin
- Fever
- Low blood pressure, this could cause dizziness when standing up quickly from a lying/seated position

Rare side effects (affecting less than 1 in 1,000 people)

- Tightness of your airways

- Shortness of breath
- Indigestion

Not known (this means the frequency cannot be estimated from the information available)

- Swelling of the face

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 to Health Products Regulatory Authority, Block A, Earlsfort Centre, Earlsfort Terrace, Saint Kevin's, Dublin, Ireland, tel.: +353 1 676 4971, e-mail: info@hpra.ie

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

5. How to store Fluimucil

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

Store in the original package to protect from moisture.

Once the contents of the sachet have been dissolved in water use this medicinal product immediately.

Do not store the solution.

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

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 contains

The active substance is acetylcysteine.

Each sachet contains 200 g

The other ingredient(s) (excipient(s)) are: saccharin, orange flavour, containing dextrose and lactose, granule of orange juice, containing sucrose, colouring agent E110, sucrose

What Fluimucil looks like and contents of the pack

Marketing Authorisation Holder and Manufacturer

ZAMBON S.p.A.

via Lillo del Duca 10

20091 Bresso (MI)

Italy

Manufacturer

Zambon Svizzera SA

Via Industria, 13

CH-6841

Switzerland

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