

FLUIMUCIL[®] A GRANULES for ORAL SOLUTION

Acetylcysteine (100 mg, 200 mg)

What is in this leaflet

1. What FLUIMUCIL is used for
2. How FLUIMUCIL works
3. Before you use FLUIMUCIL
4. How to use FLUIMUCIL
5. While you are using it
6. Side effects
7. Storage and Disposal of FLUIMUCIL
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What FLUIMUCIL is used for

FLUIMUCIL is used to treat breathing difficulties caused by too much mucus in the lungs and airways or the mucus being too sticky to cough up easily.

How FLUIMUCIL works

FLUIMUCIL contains the active ingredient 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.

Before you use FLUIMUCIL

- When you must not use it
 - If you are hypersensitive to acetylcysteine or to any of the other ingredients in FLUIMUCIL;
 - If you are suffering from active stomach/intestinal ulcer;
 - If you are suffering from phenylketonuria (genetic condition where you are unable to break down a substance called phenylalanine);
 - If you are intolerance to fructose sugar (due to the sweetener sorbitol);
 - If you are intolerance to galactose (due to the glucose and lactose);

- Do not use in children under 2 years of age.
- Before you start to use it
Always ask your doctor or pharmacist before using this product if you have
 - asthma, as you may need to be monitored closely
 - risk of gastrointestinal bleeding (eg: in stomach/intestinal ulcer or swollen veins of esophagus), as oral acetylcysteine may induce vomiting.
 - intolerance to histamine.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to pregnant, ask your doctor or pharmacist for advice before taking this medicine. FLUIMUCIL should not be used during breastfeeding, unless clearly necessary.

- Taking other medicines
Tell your doctor or pharmacist if you are taking any of the following medicines:
 - antibiotics. You should take FLUIMUCIL either two hours before or two hours after taking your antibiotics.
 - glyceryl trinitrate, medicines to treat angina attacks (chest pain)
 - carbamazepine, since acetylcysteine may decrease its effect
 - medicines that treat cough
 - activated charcoal, used to treat poisoning.

How to use FLUIMUCIL

- How much to use
 - Dissolve the content of one sachet into a glass of cold or warm water.

- Adults & adolescents over to 12 years of age: 600 mg daily, divided into one or more intakes (e.g. 200 mg 3 times daily).
- Children from 2 to 12 years of age: 100 mg 3 times daily or 200 mg twice daily.
- Long-term treatment: 400–600 mg daily, divided into one or more intakes
- *Mucoviscidosis* (genetic disorder): the same dosage as above, however, for children from 6 years of age, 200 mg 3 times daily or 600mg once daily.

- When to use it
Use as directed by your doctor or pharmacist.

- How long to use it
Continue taking FLUIMUCIL for as long as your doctor recommends.

The maximum duration for long-term treatment is 3 - 6 months

- If you forget to use it
Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)
Overdose may induce gastrointestinal symptoms such as nausea, vomiting and diarrhoea.

Contact your doctor immediately or go to the Emergency Department of your nearest

hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do
You must strictly comply with your doctor's prescription or your pharmacist's advice
- Things you must not do
Not to mix other medicines with the FLUIMUCIL solution.
- Things to be careful of
 - The use of acetylcysteine might thin the mucus and promote the cough up of mucus, especially at the beginning of treatment. If you are not able to cough up the mucus effectively, appropriate therapeutic measures shall be taken by the doctor.
 - Taking medicines that treat cough can lead to congestion of mucus and causes the risk of breathing difficulties and respiratory tract infection.

Side effects

The following undesirable effects have been observed:

- Headache;
- A ringing sound in the ears;
- A fast heart rate;
- Bleeding;
- Vomiting, diarrhoea, inflammation in your mouth and lips, abdominal pain, nausea, indigestion;
- Low blood pressure

FLUIMUCIL may cause severe allergy and serious skin reactions. Stop using FLUIMUCIL and seek medical assistance immediately if you experience any of the following symptoms:

- Severe allergy: breathing difficulties, light headedness, skin swellings or rash.

- Severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of FLUIMUCIL

- Storage
Store below 30°C, prevent from heat and humidity.

Keep out of the reach and sight of children.

- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
FLUIMUCIL A-100 and FLUIMUCIL A-200 granules for oral solution are yellow granules with a characteristic orange and slightly sulphureous odour (rotten eggs). This is a normal characteristic of this medicine and does not mean that it is not safe to use.

Ingredients

- Active ingredient:
Acetylcysteine.
- Inactive ingredients:
Orange flavour, beta carotene, aspartame, sorbitol.

MAL number

- FLUIMUCIL A-100
Granules: MAL20014506X
- FLUIMUCIL A-200
Granules: MAL20014507X

Manufacturer

Zambon Switzerland Ltd.
Via Industria 13 - 6814 Cadempino
Switzerland

Product Registration Holder

EP Plus Group Sdn. Bhd.
Block C-3-1, Plaza Mont Kiara
No 2, Jalan Kiara, Mont Kiara
50480 Kuala Lumpur.

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