

# FLUIMUCIL<sup>®</sup>

## TABLET

# A-600

# EFFERVESCENT

Acetylcysteine 600mg

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### 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 suffering from glucose-galactose malabsorption (due to the glucose);
  - 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 one effervescent tablet 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.

The approved posology refers to all the Fluimucil formulations: Fluimucil A-600 effervescent tablets, Fluimucil A-100 granules for oral solution, Fluimucil A-200 granules for oral solution.

### - 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 leads to congestion of mucus and causes the risk of breathing difficulties and respiratory tract infection.
  - If you are on a low sodium diet, it is suggested to take other salt free acetylcysteine preparations as the product contains 156.9 mg sodium per effervescent tablet.

**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](http://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<sup>®</sup> A-600 mg effervescent tablets are white circular tablets, with a characteristic lemon 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:  
Lemon flavour, aspartame, sodium hydrogen carbonate, citric acid anhydrous

- MAL number  
MAL20001835X

**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.

**Date of revision**

07/01/2021

**Serial Number**

NPRA (R2/1) 200702/473