

FLUIMUCIL 100mg/ 5ml Oral Solution

N-Acetylcysteine (100mg/ 5ml)

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What FLUIMUCIL 100mg/ 5ml Oral Solution is used for

FLUIMUCIL 100mg/ 5ml Oral Solution 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 100mg/ 5ml Oral Solution works

FLUIMUCIL 100mg/ 5ml Oral Solution 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.

Before you use FLUIMUCIL 100mg/ 5ml Oral Solution

- When you must not use it
 - If you are allergic to acetylcysteine or to any of the other ingredients in FLUIMUCIL (listed in subsection "Ingredients").
 - Do not use FLUIMUCIL in children under 2 years of age.
- Before you start to use it

Talk to your doctor or pharmacist before using FLUIMUCIL if

- you have asthma as you may need to be monitored closely. Should difficulty in breathing occur, you should stop taking FLUIMUCIL and seek medical assistance immediately.
- you have or have had stomach/ intestinal ulcer, especially if you are taking other medicines known to cause gastrointestinal problems.
- you are intolerant to histamine, as allergic symptoms may occur.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any of the following medicines:

- activated charcoal as it can reduce the efficacy of FLUIMUCIL.
- oral antibiotics. You should take FLUIMUCIL either two hours before or two hours after taking your antibiotics (except Loracarbef).
- glyceryl trinitrate, medicines to treat angina attacks (chest pain). Taking this medicine with FLUIMUCIL may cause a drop in blood pressure and headache.

Do not take FLUIMUCIL if you are using cough medicine, as they can lead to a mucus accumulation in lung.

How to use FLUIMUCIL 100 mg/ 5ml Oral Solution

How much to use

- Adults and adolescents over 12 years of age: 600mg daily, divided into one or more administrations (e.g., 10ml 3 times daily or 30ml daily).
- Children from 2 to 12 years of age: 300mg (e.g., half measuring cup (5ml) 3 times daily) or 400mg (e.g., one 10ml measuring cup twice daily).

Special posologies:

- Long-term treatment: 400 – 600 mg daily, divided into one or more administrations
- Mucoviscidosis: the same dosage as above, however, for children from 6 years of age, 200mg 3 times daily or 600mg once daily

Shake before use.

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

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
FLUIMUCIL must not be mixed with other medicinal products.
- Things to be careful of
 - This medicine has a sulphur smell and it is the normal characteristic of the medicine due to the presence of acetylcysteine. This does not indicate an alteration of the product.
 - 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.
 - This medicine contains 38.2mg sodium per 10ml. This should be taken into account if you have impaired kidney function or on a low-sodium diet.
 - This medicine contains methyl parahydroxybenzoate. This substance may cause allergic reactions (also of delayed type).
 - This medicine contains small amounts of ethanol (alcohol), less than 100mg per 10ml.
 - This medicine contains 19.8mg propylene glycol per 10ml.
 - N-acetylcysteine may interfere with certain blood and urine tests (colorimetric method for total salicylate assay and urine testing for ketones).

Side effects

The following undesirable effects have been observed:

Uncommon (may affect up to 1 in 100 people):

- allergic reactions
- headache
- ringing in the ears
- increased heart rate
- vomiting
- diarrhoea
- inflammation in mouth and lips
- abdominal pain
- nausea
- urticaria
- rash
- sudden swelling of the face, lips, tongue or throat that may cause difficulty swallowing or breathing (angioedema)
- itching
- fever
- blood pressure decreased

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

- tightness of airways
- shortness of breath
- indigestion

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

- severe allergic reactions (anaphylactic shock, anaphylactic/anaphylactoid reaction),
- bleeding

Not known (frequency cannot be estimated from the available data)

- airways obstruction
- facial swelling

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 100 mg/ 5ml Oral Solution

- Storage
Store below 25°C.
Keep out of the reach and sight of children.

Once opened, the oral solution has a shelf life of 15 days.

- 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
Clear or slightly opalescent, colourless solution with a characteristic odour of raspberry.

Box containing 100 ml or 200 ml oral solution in glass bottle, supplied with a measuring cup.

- Ingredients
 - Active ingredient:
Acetylcysteine.
 - Inactive ingredients:
Methyl parahydroxybenzoate, sodium benzoate, disodium edetate, carmellose sodium, sodium cyclamate, sucralose, raspberry flavour (contains propylene glycol, ethyl alcohol and flavouring substances), saccharin sodium, sodium hydroxide, purified water.

- MAL number
MAL23036002XZ

Manufacturer

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Product Registration Holder

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