## FLUIMUCIL<sup>®</sup> 100mg - Patient Information Leaflet

## What is FLUIMUCIL® 100mg?

FLUIMUCIL<sup>®</sup> 100mg contains the active ingredient Acetylcysteine that belongs to a group of medicines called mucolytics.

FLUIMUCIL<sup>®</sup> 100mg acts by quickly breaking down mucus that obstructs the airways and causes coughing. It facilitates the removal of thick mucus to ease congestion in throat and lungs.

## What is FLUIMUCIL® 100mg used for?

FLUIMUCIL<sup>®</sup> 100mg is used as a mucolytic agent in respiratory conditions associated with excessive mucus production.

## What you need to know before taking FLUIMUCIL® 100mg

Do not take FLUIMUCIL<sup>®</sup> 100mg if you are allergic to Acetylcysteine or any of the other ingredients of this medicine.

## How do I take FLUIMUCIL® 100mg sachet?

Adults and children above 6 years 2 sachets FLUIMUCIL<sup>®</sup> 100mg, 2-3 times a day

Children (2 – 6 years of age) 1 sachet FLUIMUCIL<sup>®</sup> 100mg from 2 to 4 times a day, accordingly to the age

Dissolve the content of the sachets in a glass containing a small quantity of water, mixing it, if necessary, with a spoon. A palatable solution is thus obtained to be drunk immediately.

It is preferable not to mix other drugs with FLUIMUCIL<sup>®</sup> 100mg solution. It is advisable to administer antibiotics 2 hours apart from Acetylcysteine.

The duration of treatment should be 5 to 10 days. if you do not feel better or if you feel worse, you must talk to a doctor.

## Warnings and Precautions

Mucolytic agents can induce respiratory obstruction in children under 2 years of age. Due to the physiological characteristics of the airways in this age group, the ability to expectorate may be limited. Therefore mucolytic agents should not be used in children under 2 years of age.

Caution should be taken in patients suffering from or with a history of peptic ulcer.

Patients suffering from bronchial asthma must be strictly controlled during the therapy; if difficulty in breathing (bronchospasm) occurs, the treatment must immediately be suspended.

FLUIMUCIL<sup>®</sup> 100mg contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FLUIMUCIL<sup>®</sup>. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

FLUIMUCIL® 100mg contains colouring agent E110: it may cause allergic reactions

The possible presence of a sulphurous odour does not indicate an alteration of the product but it is a characteristic of the active ingredient contained in this preparation.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, cough suppressants as their ability to reduce cough reflex may lead to the accumulation of bronchial secretions.

## Use during pregnancy and lactation

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

## Possible side effects

Like all medicines, FLUIMUCIL<sup>®</sup> 100mg can cause side effects, although not everybody gets them. In very rare cases, severe allergic reactions may occur such as anaphylactic shock and severe skin reaction.

In rare cases the oral administration can be followed by shortness of breath, upset stomach and difficulty in breathing (bronchospasm).

The most frequent side effects are headache, increased heart rate, inflammation of the mouth (stomatitis), itching (pruritus), hives (urticaria), nausea, vomiting, abdominal pain, fever, decrease in the blood pressure, diarrhoea and noises in the ears.

If you get any side effects, talk to your doctor or pharmacist.

## <u>Overdose</u>

If you have taken more FLUIMUCIL<sup>®</sup> 100mg than you should, you might experience nausea, vomit or diarrhoea. Contact your doctor.

## How do I store FLUIMUCIL<sup>®</sup> 100mg?

Store below 25°C. Protect from heat and humidity.

## What does FLUIMUCIL® 100mg contain?

- The active substance is Acetylcysteine. Each sachet contains 100 mg Acetylcysteine.

- The other ingredients are: sucrose, colouring agent E 110, excipients q.s. to 5 grams.

## Packaging

Each pack contains - 30 sachets of 100mg Acetylcysteine

# Manufactured by

Zambon Switzerland Ltd. 6814 Cadempino (Switzerland)

KEEP OUT OF SIGHT AND REACH OF CHILDREN