Fluimucil mucolytic 100mg / 5ml Syrup
N-acetylcysteine

Pharmacotherapeutic category
Fluimucil Mucolytic is a thinner mucus.

Therapeutic indications
Fluimucil Mucolytic is used for the treatment of respiratory disorders characterized by hyper-dense and sticky.

Contraindications
Hypersensitivity to the active substance or to any of the excipients.
The drug is contraindicated in children less than 2 years.
Pregnancy and lactation (see "what to do during pregnancy and bed rest").

Precautions for use
The mucolytics can induce bronchi al obstruction in children less than 2 years. In fact, the ability of the bronchial mucus drainage is limited in this age group, because of the physiological characteristics of the respiratory tract. They should therefore not be used in children younger than 2 years (see "When it should not be used").
The administration of N-acetylcysteine, especially at the beginning of the treatment, can fluidize bronchial secretions and increase at the same time the volume.

Interactions
Inform your doctor or pharmacist if you have recently taken any other medicines, including medicines obtained without a prescription.
Drug interaction medication
Antitussives medicines and N-acetylcysteine must not be taken simultaneously as the decrease of the cough reflex may lead to an accumulation of bronchial secretions. Activated charcoal may reduce the effect of N-acetylcysteine.
It is advisable not to mix other drugs with the Fluimucil Mucolytic solution. The information available about the interaction antibiotic-N-acetylcysteine are based on in vitro tests, in which the two substances, which showed a decreased activity of the antibiotic were mixed. However, as a precaution, it is recommended to take oral antibiotics for at least two hours after the administration of N-acetylcysteine. It has been shown that the simultaneous administration of nitroglycerin and N-acetylcysteine cause significant hypotension and determines temporal artery dilation with possible onset of headache.
If you are using other medications, ask your doctor or pharmacist.
Drug-lab test
The N-acetylcysteine can cause interference with the assay method for the colorimetric determination of salicylates. The N-acetylcysteine can interfere with the test for the determination of urine ketone.

Special warnings
The possible presence of a sulfurous odor does not indicate alterations of the preparation but is own of the active substance contained in it.
When it can be used only after consulting your doctor
Patients with asthma should be monitored closely during therapy, if it appears bronchospasm, treatment must be discontinued immediately.
You should consult your doctor, even if these troubles have arisen in the past.
It requires special attention the use of the medicine in patients with peptic ulcer or a history of peptic ulcer, especially in case of simultaneous intake of other drugs with a known gastrolesivo effect.
What to do during pregnancy and lactation
Ask your doctor or pharmacist before taking any medicine.
In Pregnancy and Fluimucil Mucolytic it should be used only after consulting the doctor and assessing with him the individual risk / benefit case. Consult your physician if you suspect they are pregnant or planning a pregnancy wish.

Effects on ability to drive and use machines
Fluimucil Mucolytic does not affect the ability to drive or operate machinery.

Important information about some of the ingredients
The product contains parahydroxybenzoates that may cause allergic reactions of delayed and, more rarely, immediate reactions with bronchospasm and urticaria. The product contains 16.6 mg sodium per dose to keep in mind in the case of patients with impaired renal function or patients on a controlled sodium diet.

**Dose, method and time of administration**
Adults: 10 ml of syrup (one scoop) corresponding to 200 mg of N-acetylcysteine, 2-3 times a day.
Children over the age of two years: 5 ml of syrup (1/2 scoop), equal to 100 mg of N-acetylcysteine, from 2 to 4 times per day according to the age.
Warning, do not exceed the prescribed dose unless recommended by your physician.

When and for how long
The duration of treatment is 5-10 days. Consult your doctor if the disorder occurs repeatedly or if you have noticed any recent change in its characteristics.
Shake syrup before use. Once opened, the syrup is valid for 15 days.

**Overdose**
Overdose can cause gastrointestinal symptoms such as nausea, vomiting and diarrhea.
If accidentally swallowed / taken an overdose of Fluimucil Mucolytic, immediately notify your doctor or contact the nearest hospital.
If you have any further questions on the use of Fluimucil Mucolytic, contact your doctor or pharmacist.

**Side effects**
Like all medicines, Fluimucil Mucolytic can cause side effects, although not everybody gets them.
The following is a table showing the frequency of adverse reactions reported after taking N-acetylcysteine by mouth:

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Adverse Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncommon</td>
<td>(&gt; / = 1 / 1,000, &lt;1/100) Rare</td>
</tr>
<tr>
<td>(&gt; / = 1 / 10,000, &lt;1 / 1,000) Very rare (&lt;1 / 10,000) Not known</td>
<td></td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>Hypersensitivity Anaphylactic shock, anaphylactic / anaphylactoid</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
</tr>
<tr>
<td>Ear and labyrinth</td>
<td>Tinnitus</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>Tachycardia</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Hemorrhage</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Bronchospasm, dyspnoea bronchial obstruction</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Vomiting, diarrhea, stomatitis, abdominal pain, nausea, dyspepsia</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Urticaria, rash, angioedema, pruritus</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia Oedema of the face</td>
</tr>
<tr>
<td>Investigations reduced blood pressure</td>
<td></td>
</tr>
</tbody>
</table>

In very rare cases, there was the appearance of serious skin reactions in temporal connection with the intake of N-acetylcysteine, such as Stevens-Johnson syndrome and Lyell's syndrome.
Although in most cases has been identified to at least one other suspected drug most probably involved in the genesis of these mucocutaneous syndromes, in case of mucocutaneous disorders should consult your doctor and taking N-acetylcysteine should be stopped immediately.
Some studies have confirmed a reduction of platelet aggregation while taking N-acetylcysteine. The clinical significance of these findings has not yet been defined.
Compliance with the instructions contained in the explanatory leaflet reduces the risk of side effects. These side effects are usually transient.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Ask for and fill in the report form undesirable effects form available at the pharmacy (B).

**Shelf life and storage**
See expiry date on the package. This date is based on the product unopened and properly stored. Caution: Do not use the medicine after the expiration date on the package. Once opened, the syrup is valid for 15 days. KEEP THE MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer use. This will help protect the environment. It is important to always have the product information, thus keep both the box and the package leaflet.

**Composition**
One vial contains: Active ingredient: N-acetylcysteine 4 g (corresponding to 20 mg per ml of syrup). Excipients: Methyl parahydroxybenzoate, sodium benzoate, disodium edetate, sodium carboxymethylcellulose, sodium cyclamate, sucralose, raspberry flavor, sodium saccharin, sodium hydroxide, purified water.

**Pharmaceutical form and contents**
Fluimucil Mucolytic 100 mg / 5 ml is presented in the form of syrup. The content of the package is 1 bottle of 100 ml with 1 scoop.