

PACKAGE LEAFLET: Information for the user

MUKOL

Syrup – 100 mg / 5 ml

(Carbocisteine)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Mukol is and what it is used for
2. Before you take Mukol
3. How to take Mukol
4. Possible side effects
5. How to store Mukol
6. Contents of the pack and other information

1. WHAT MUKOL IS AND WHAT IT IS USED FOR

The syrup Mukol contains the active substance carbocisteine. Carbocisteine is a mucolytic agent. The molecule of carbocisteine blocks chemically the sulfhydryl group (-SH), which is responsible for the mucus properties. In this way carbocisteine acts as a mucolytic. It affects also the synthesis of sialomucin by increasing its quantity, making easier the removal of secretions. Carbocisteine decreases the hyperplasia and hypertrophy of the zone that secretes mucus and at the same time acts locally as an antiphlogistic. By normalizing the secretion, carbocisteine acts as a regulator even in other structures where mucoproteine is synthetized e.g.: gastrointestinal apparatus, urogenital apparatus and middle ear.

Mukol is indicated in the treatment of respiratory tract disorders associated with excessive, viscous mucus (bronchitis; bronchial asthma; pulmonary tuberculosis complicated with chronic bronchitis; rhinitis; sinusitis; laryngitis).

Your doctor may have given Mukol for another purpose. Ask your doctor if you want to know why this drug was given to you.

2. BEFORE YOU TAKE MUKOL

Do not take Mukol if you suffer from:

- known hypersensitivity to carbocysteine or to the excipients of the syrup;
- active gastroduodenal ulcer;
- glomerulonephritis;
- acute cystitis.

It should not be given to children under 2 years of age.

Warning and precautions

Ask your doctor before taking Mukol!

Mukol should be used with caution in patients with a history of peptic ulcer.

Mukol should be used with caution also in asthmatic patients with a history of bronchial spasm (tightening of the airways muscles), severe respiratory insufficiency and in debilitated patients due to the decrease of the cough reflex as there is risk of obstruction of the airway as a consequence of the increase of the quantity of secretions. In case of significant hypersecretion, the suction of tracheobronchial secretions may be necessary.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Mukol.

Please inform your doctor or pharmacist if you are taking or have recently taken other medicines, including those without prescription.

Do not forget to inform your doctor for the treatment with Mukol if you receive any other medicine during treatment.

No interaction of carbocisteine with other drugs has been noticed.

Do not take cough calming or secretion-drying medicines, because these have an effect contrary to that of carbocisteine.

Caution is recommended in patients taking concomitant drugs that may cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, the treatment should be interrupted.

Mukol with food and drinks

No data.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or planning to become pregnant. During pregnancy this drug can be taken only if it is absolutely necessary, but it is recommended to be avoided, especially during the first trimester.

Always consult your doctor before taking Mukol during pregnancy.

Breastfeeding

There are no data about the use of Mukol during breastfeeding, however as a precaution, Mukol should not be taken during this period.

Driving and using machines

There are no effects noticed when driving or using machines.

Important information about some of the excipients of Mukol

Mukol contains:

- methyl hydroxybenzoate; may cause allergic reactions (possibly delayed);
- sucrose; if you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving them this medicinal product; Mukol contains 5.6 g sucrose / 12.5 ml; this should be taken into account in patients with diabetes mellitus; sucrose may be harmful to the teeth during chronic use;
- sodium; Mukol contains approximately 41.65 mg sodium / 12.5 ml; to be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE MUKOL

Always take Mukol exactly as your doctor or pharmacist has told you. If you are not sure, check with your doctor or pharmacist. If you feel that the effects of Mukol are too strong or too weak, talk to your doctor or pharmacist.

The dosage is presented below:

Children from 2 to 5 years: 50 - 100 mg (2.5 ml – 5 ml), 4 times daily.

Children from 5 to 12 years: 250 mg (12.5 ml), 3 times daily.

If you take more Mukol than you should

If you take more Mukol than the amount that should be taken, or if children have taken it by mistake, please contact your doctor, hospital, or call the emergency to get an opinion about the risk and advice on the actions to be taken.

In acute carbocisteine overdose, gastrointestinal disorders are the only symptoms noticed and a non-active treatment is seen necessary; however symptomatic treatment must be done.

If you forget to take Mukol

If you forget a dose (or more than one dose), take the next dose in its usual time.

Do not take a double dose (or higher) to make up the missed dose (doses).

If you have further questions about the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mukol may cause side effects, although not everybody manifests them.

Mukol is well tolerated in the recommended doses. Inform your doctor if the side effects presented below appear:

- nausea, vomiting;
- headache;
- gastric disorders;
- diarrhea;
- gastrointestinal bleeding;

- exanthema;
- hypersensitivity reactions;
- Stevens-Johnson syndrome;

If any of the side effects gets worse, or if you notice side effect not listed in this leaflet, talk to your doctor or pharmacist. If the side effects mentioned above occur, the treatment with Mukol should be interrupted and you should talk with your doctor or pharmacist.

5. HOW TO STORE MUKOL

Keep out of the sight and reach of children!

Do not use Mukol after the expiry date which is stated on the package!

Store below 25°C!

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Mukol 100 mg / 5 ml syrup contains:

The active substance is carbocysteine.

5 ml syrup contain 100 mg of carbocysteine.

The excipients are: citric acid monohydrate, sodium hydroxide, disodium-EDTA, ethanol (96 per cent), banana essence, methyl hydroxybenzoate (nipagin), sucrose and purified water.

Content of the pack

Carton box with 1 amber glass bottle of 150 ml, with a dosing pipette and a dosing cup.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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This leaflet was last revised in November 2023.