PACKAGE LEAFLET:
Information for the patient

MUKOLITINE A – Syrup 250 mg / 5 ml
MUKOLITINE P – Syrup 100 mg / 5 ml
(Carbocisteine)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- 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 Mukolitine is and what it is used for?
2. What you need to know before you take Mukolitine?
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1. WHAT MUKOLITINE IS AND WHAT IT IS USED FOR
The syrup Mukolitine 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.
Mukolitine is indicated in the treatment of the respiratory apparatus disorders associated with significant mucus secretion:
- bronchitis;
- bronchial asthma;
- pulmonary tuberculosis complicated with chronic bronchitis;
- rhinitis;
- sinusitis;
- laryngitis.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MUKOLITINE
Do not take Mukolitine if you suffer from:
- known hypersensitivity to carbocisteine or to the other excipients of the syrup;
- active gastroduodenal ulcer;
- glomerulonephritis;
- acute cystitis.

It should not be taken by children under 2 years of age.

Warning and precautions
Ask your doctor before taking Mukolitine!
Mukolitine should be taken with caution in patients with a history of peptic ulcer. In case of significant hypersecretion, the suction of tracheobronchial secretions may be necessary. Caution is recommended in the elderly or those taking concomitant drugs that may cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, the treatment should be interrupted.

Taking other medicines
Concomitant treatment with other medicines may affect or be affected by Mukolitine.
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 Mukolitine if you recieve any other medicine during treatment.
No interaction of carbocisteine with other drugs has been noticed.
Caution is recommended in those taking concomitant drugs that may cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, the treatment should be interrupted.

Mukolitine 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. Always consult your doctor before taking Mukolitine during pregnancy.

Breast-feeding
There are no data about the use of Mukolitine during breast-feeding, however as a precaution, Mukolitine 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 Mukolitine
Mukolitine contains:
- methyl hydroxybenzoate; may cause allergic reactions (possibly delayed)
- sucrose; if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product; Mukolitine A contains 6.75 g sucrose / 15 ml while Mukolitine P 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; Mukolitine A contains approximately 133.58 mg sodium / 15 ml while Mukolitine P contains approximately 41.65 mg sodium / 12.5 ml; to be taken into consideration by patients on a controlled sodium diet.

Mukolitine A contains ethanol; it can be harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

3. HOW TO TAKE MUKOLITINE
Always take Mukolitine 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 Mukolitine are too strong or too weak, talk to your doctor or pharmacist.

Mukolitine A – syrup 250 mg / 5 ml
The dosage is presented below:
This drug is given orally as a syrup in adults and children over 12 years, in a dose of 750 mg, three times daily (15 ml or 3 teaspoons syrup, 3 times daily). The dose is reduced in 1/3 if an improvement is noticed during treatment.
Bronchitis: The administration of carbocisteine in a dose of 750 mg three times daily for 6 months has improved the lung function in patients with chronic bronchitis, but it appeared to have no effect on the frequency of acute exacerbations. Carbocisteine also improves the sputum rheology.

Mukolitine P – syrup 100 mg / 5 ml
The dosage is presented below:
Children from 2 to 5 years should take 50 – 100 mg (2.5 ml – 5 ml), 4 times daily. While children from 5 to 12 years should take 250 mg (12.5 ml), 3 times daily.

If you take more Mukolitine than you should
If you take more Mukolitine than the amount that should be taken, or if the 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 neccesary; however symptomatic treatment must be done.

If you forget to take Mukolitine
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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Mukolitine may cause side effects, although not everybody manifests them. Mukolitine is well tolerated in the recommended doses. Inform your doctor if the side effects presented below appear:
- nausea;
- headache;
- gastric disorders;
- diarrhea;
- gastrointestinal bleeding;
- exanthema;
- hypersensitivity reactions;
- Stevens - Johnson syndrome.

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

5. HOW TO STORE MUKOLITINE
Keep out of the sight and reach of children!
Do not take Mukolitine after the expiry date which is stated on the package!
Store below 25º C!
Keep in the original package to protect from light!

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Mukolitine A – syrup 250 mg / 5 ml contains:
The active substance is carbocisteine.
5 ml syrup contain 250 mg of carbocisteine.
The other ingredients are: citric acid monohydrate, sodium hydroxide, disodium - EDTA, ethanol, essence banana, methyl hydroxybenzoate (nipagin), sucrose and purified water.

What Mukolitine P – syrup 100 mg / 5 ml contains:
The active substance is carbocisteine.
5 ml syrup contain 100 mg of carbocisteine.
The other ingredients are: citric acid monohydrate, sodium hydroxide, disodium - EDTA, ethanol, essence banana, methyl hydroxybenzoate (nipagin), sucrose and purified water.

Content of the pack
Mukolitine A – syrup 250 mg / 5 ml
Carton box with 1 glass bottle of 150 ml.

Mukolitine P – syrup 100 mg / 5 ml
Carton box with 1 glass bottle of 150 ml.

Explanatory of the illustration icons on the packaging:
Without medical prescription.
Content. Warning. Syrup.

Marketing Authorisation Holder (MAH) and Manufacturer:
PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in March 2017.

SPECIFICATION

CROPING AREA 12 x 19 cm

PAY ATENTION, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.