

Package leaflet: Information for the patient

Mucotal Adult Syrup

Carbocysteine 250 mg / 5ml

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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 Mucotal Adult is and what it is used for
2. What you need to know before you take Mucotal Adult
3. How to take Mucotal Adult
4. Possible side effects
5. How to store Mucotal Adult
6. Contents of the pack and other information

1. What Mucotal Adult is and what it is used for

Mucotal Adult contains the active substance carbocysteine. It belongs to a group of medicines called “mucolytics”. It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up. This medicine is intended for use in adults (aged over 15 years) who have had a recent respiratory disorder with difficulty expectorating (i.e. difficulty coughing up phlegm).

2. What you need to know before you take Mucotal Adult

Do not take Mucotal Adult and talk to your doctor if:

- You are allergic (hypersensitive) to carbocysteine or any of the other ingredients of this medicine (listed in section 6) particularly to methyl paraben and other paraben salts.
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- if you have a stomach or intestinal ulcer.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Mucotal Adult:

A medical opinion is necessary:

- in the event of thick and purulent sputum or fever;
- if you suffer from chronic (long-term) bronchial or pulmonary disease;
- if you have a history of gastroduodenal ulcers (affecting the stomach or intestine);
- if you are elderly;
- if you are also taking medicines that are likely to cause bleeding in the stomach or intestine, treatment should be stopped.

Precautions for use

This medicine should always be accompanied by voluntary coughing attempts, allowing expectoration. Do not take antitussive medicines (used to calm coughing) or medicines that dry up bronchial secretions during the period of treatment with carbocysteine.

Childrens and adolescents:

Mucotal Adult is not recommended for children under 15 years old. A lower strength syrup called “Mucotal Pediatric 100 mg / 5 ml syrup” is available for use in children under 15 years old.

Other medicines and Mucotal Adult:

There are no known interactions of Mucotal Adult with other medicines. In order to prevent possible interactions, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding:

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant. This medicine should not be taken during the first three months of your pregnancy.
- You are breast-feeding or planning to breast-feed. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines:

Be careful driving or operating machinery while taking this medicine. Impaired alertness, linked to the presence of alcohol in this medicine, can make driving or machine operating dangerous.

Important information about some of the ingredients of Mucotal Adult:

This medicine contains:

- Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.
- Ethanol: This medicine contains 13% ethanol (alcohol). A 15 ml dose of this medicine contains up to 1550 mg of ethanol; this is about the same amount of alcohol as 39 ml of beer or 16.25 ml of wine per dose. This can be harmful for those suffering from alcoholism. It should also be taken into account in pregnant or breast-feeding women and high risk groups such as patients with liver disease or fits (epilepsy).
- Sodium: This medicine contains 97 mg of sodium in each 15ml dose. Take this into consideration if you are on a controlled sodium diet.
- Methyl parahydroxybenzoate and a colouring agent – FDC Yellow 6: Both of these ingredients may cause allergic reactions (these may not happen straight away). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.

3. How to take Mucotal Adult

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Taking this medicine:

- Take this medicine by mouth.
- If you feel that this medicine is too weak or too strong, do not change the

dose yourself, but ask your doctor.

How much to take:

- Usual dose, for adults and Adolescents over 15 years old, is 15 ml three times each day (3 teaspoonfuls or 1 tablespoonful).
- If your symptoms improve, your dose may be lowered to 10 ml (2 teaspoonfuls), three times, each day.

Duration of treatment:

The duration of treatment should be brief.

Do not exceed 5 days of treatment without medical advice.

If you take more Mucotal Adult than you should

If you take more of this medicine than you should, tell a doctor or go to a hospital straight away.

Take this medicine pack with you. This is so the doctor knows what you have taken. If you take too much of this medicine, it is likely that you will get an upset stomach (gastrointestinal disturbance).

If you forget to take Mucotal Adult

If you forget a dose, do not worry. Just wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Gastrointestinal disorders, such as stomach pain, nausea, vomiting and diarrhea. If these occur, the dosage should be reduced.
- Bleeding in the stomach or intestine. Treatment should be stopped.
- Allergic skin eruption and anaphylactic reactions such as hives, itching, appearance of plaques or spots on the skin, and swelling of the face and/or neck that can lead to difficulty breathing and be lifethreatening (angioedema). In this case, you should stop treatment and see your doctor immediately.
- Brown or purple plaques which can cause skin discoloration (fixed drug eruption). In this case, you should see your doctor immediately.
- Appearance of spots, sometimes with blisters, on the skin that can also affect the mouth (erythema multiforme), appearance of blisters with detachment of the skin that can spread over the whole body and may be life-threatening (Stevens-Johnson syndrome).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mucotal Adult

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C.

- Do not use this medicine if you notice any change in the appearance of the oral solution.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mucotal Adult contains

- The active substance is carbocysteine. Each 5 ml of syrup (1 teaspoonful) contains 250 mg of carbocysteine.
- The other ingredients are water, ethanol, propylene glycol, citric acid, sodium saccharine, sodium hydroxide, sodium citrate, sucrose, methylparahydroxybenzoate (or methylparaben), FDC Yellow 6 and caramel flavour.

What Mucotal Adult looks like and contents of the pack

Mucotal Adult is an Orange syrup caramel flavored.

Mucotal Adult is available in 150 ml bottle.

Marketing Authorisation Holder and Manufacturer

Pharmaline, sal – Lebanon

P.O. Box 90201 Jdeidet-El-Metn, Lebanon

Contact us: pharmaline@maliagroup.com

Website: www.pharmaline.com.lb

Reg. N°. for Mucotal Adult: 27807/94

This is a medicament:

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers
Union of Arab Pharmacists

This leaflet was last revised in July 2022.