

carbomuc adults

Carbocysteine 5%

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take **carbomuc adults** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 5 days.
- 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.

In this leaflet:

1. What **carbomuc adults** is and what it is used for.
2. Before you take **carbomuc adults**.
3. How to take **carbomuc adults**.
4. Possible side effects.
5. How to store **carbomuc adults**.
6. Further information.

1. WHAT carbomuc adults IS AND WHAT IT IS USED FOR

It belongs to the group of medicines called mucolytics (preparations for cough and cold). Its active substance (carbocysteine) acts reducing the viscosity of mucus, fluidifying it and enhancing clearance.

This medicine is indicated for treatment of bronchial secretion disorders, in particular during acute bronchial diseases: acute bronchitis and acute episode of chronic bronchitis.

2. BEFORE YOU TAKE carbomuc adults**Do not take carbomuc adults:**

- If you are allergic (hypersensitive) to carbocysteine or any of the other ingredients of this medicine (see paragraph **Important information about some of the ingredients**).
- If you suffer from a stomach or duodenal ulcer.
- If you have asthma or any serious respiratory illnesses.

Take special care with carbomuc adults:

During the first days of treatment you can see an increase in mucus and phlegms, that will decrease over treatment.

Taking other medicines:

Do not take **carbomuc adults** concomitantly with antitussive medicines (against cough) or with those reducing bronchial secretions, as it can cause an accumulation of fluidised mucus.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding:

It is not recommended to use this medicine in pregnant and nursing women.

Ask your doctor or pharmacist for advice before taking any medicine.

Important for women:

If you are pregnant or think you may be, ask your doctor before taking this medicine. The use of medicines during pregnancy can be dangerous for the embryo or the foetus and must be controlled by your doctor.

Driving and using machines:

It should be used with caution by persons whose activities require concentration and who have noticed adverse events such as light-headedness and dizziness with this medicine.

Important information about some of the ingredients of carbomuc adults:

This medicine contains orange yellow (E-110). It may cause allergic-type reactions, including asthma in patients allergic to acetylsalicylic acid.

This medicine contains methyl and propyl parahydroxybenzoate. This may cause allergic reactions (possibly late).

This medicine contains 8,9 mg of sodium per ml, which should be taken into account by patients on a low salt diet.

This medicine contains maltitol (E-965). If your doctor has indicated that you suffer intolerance to some sugars, ask him before taking this medicine.

3. HOW TO TAKE carbomuc adults

Ask your doctor or pharmacist if you are not sure.

The standard doses are:

Adults and children over 12 years of age: 15 ml of oral solution (750 mg of carbocysteine) 3 times a day, which means a daily maximum of 45 ml of oral solution (2.25 g of carbocysteine). Once you notice an improvement, you can reduce the dose up to 10 ml of oral solution (500 mg of carbocysteine) 3 times a day, equivalent to a daily maximum of 30 ml of the solution (1.5 g of carbocysteine).

Children under 12 years of age: It must not be used in this age group.

It is recommended to drink a glass of water after each dose and plenty of liquid at daytime.

If the symptoms worsen or persist after 5 days of treatment or the following occur: fever, skin rash, persistent headache or sore throat, you should ask a doctor.

If you take more carbomuc adults than you should:

If you have taken more **carbomuc adults** than you should, ask immediately a doctor or pharmacist, or call the Toxicology Information Service, telephone number: 91 562 0420, specifying the medicine and amount taken.

If you forget to take carbomuc adults:

Do not take a double dose to make up for forgotten individual doses.

If you have any doubt about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **carbomuc adults** can cause side effects, although not everybody gets them.

Common adverse events (at least in 1 of every 100 patients):

Gastrointestinal disorders, such as nausea, vomiting, diarrhoea, or dyspepsia. In some cases it may be useful to reduce the dose administered.

Rare adverse events (at least in 1 of every 10,000 patients):

Hypersensitivity reactions, bronchial spasm, gastrointestinal bleeding, headache, dizziness, skin rash, itching.

Very rare adverse events (less than 1 of every 10,000 patients):

Bronchial spasm, fixed drug erythema.

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.

5. HOW TO STORE carbomuc adults

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the package, after the abbreviation "EXP". The expiry date refers to the last day of that month.

Do not store at a temperature above 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What carbomuc adults contains:**

- 5 ml of solution contains 250 mg of carbocysteine as active substance.
- The other ingredients are: liquid maltitol (E-965), sodium hydroxide (E-524), sodium citrate (E-331), propylene glycol (E-1520), hydroxyethylcellulose, monohydrate citric acid, methylparahydroxybenzoate (sodium salt), sodium saccharine, orange flavour, propylene-parahydroxybenzoate (sodium salt), sunset yellow (E-110), purified water.

What carbomuc adults looks like and contents of the pack:

carbomuc adults is supplied in oral solution. Each package contains 125 ml of oral solution and a dosing cup.

Marketing Authorisation Holder and Manufacturer:

Laboratorios Cinfa, S.A.
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