

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

CARBOCISTEINE 375MG CAPSULES

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 symptoms 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 (see section 4).

In this leaflet:

1. What carbocisteine capsules are and what they are used for
2. Before you take carbocisteine capsules
3. How to take carbocisteine capsules
4. Possible side effects
5. How to store carbocisteine capsules
6. Further information

1. WHAT CARBOCISTEINE CAPSULES ARE AND WHAT THEY ARE USED FOR

Carbocisteine 375mg Capsules (called carbocisteine capsules in this leaflet) contain a medicine called carbocisteine. This belongs to a group of medicines called 'mucolytics'. It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up. Carbocisteine capsules are used for problems with the breathing passages (respiratory tract). These problems happen when too much mucus is made or the mucus is too sticky.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CARBOCISTEINE

Do not take this medicine and tell your doctor if:

- You are allergic to carbocisteine or any of the other ingredients of carbocisteine capsules (listed in section 6)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue

- You have an ulcer in your stomach or gut
Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking carbocisteine capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if:

- You are elderly.
- Have had an ulcer in your stomach or gut.
- You are taking other medicines known to cause bleeding in the stomach.

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.

Carbocisteine capsules contain:

- **Lactose.** This medicine contains lactose. This is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.
- **Sunset yellow (E110):** May cause allergic reactions. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.

3. HOW TO TAKE CARBOCISTEINE CAPSULES

Always take carbocisteine capsules exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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

Adults (including the elderly)

- Usual dose is two capsules, 3 times each day
- If your symptoms improve, your dose should be lowered to one capsule, 4 times, each day

Children

- Carbocisteine capsules are not recommended for use in children less than 2 years of age. A paediatric syrup is available for use in children

If you take more carbocisteine capsules than you should

If you take more carbocisteine capsules than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. If you take too many carbocisteine capsules, it is likely that you will get an upset stomach (gastrointestinal disturbance).

If you forget to take carbocisteine capsules

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, carbocisteine capsules can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department.

Stop taking carbocisteine capsules and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, skin eruptions, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- You have blistering or bleeding of the skin, including around your lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'
- Blood in your vomit or black tarry stools.

Other side effects (frequency not known):

- Being sick (vomiting), nausea, diarrhoea and discomfort in the upper abdomen (epigastric discomfort).

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.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple App Store.

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

5. HOW TO STORE CARBOCISTEINE CAPSULES

Keep this medicine out of sight and reach of children.

Do not use carbocisteine capsules after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What carbocisteine capsules contains:

- Each capsule contains 375mg of the active substance, carbocisteine.
- The other ingredients are magnesium stearate (E572), anhydrous colloidal silica (E551, lactose monohydrate, sodium lauril sulphate, gelatin, quinoline yellow (E104), sunset yellow (E110) and titanium dioxide (E171)

What carbocisteine capsules look like and contents of the pack

Carbocisteine capsules are yellow and printed 'Mucodyne 375' in black.

They are available in blister packs containing 6, 18, 30 or 120 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London EC4A 1JP, United Kingdom

Manufacturer:

Famar Health Care Services Madrid, S.A.U., Avda. Leganés, 62, Alcorcón 28923 (Madrid) Spain

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