

Package leaflet: Information for the user

Carbocisteine

375 mg Capsules, hard
carbocisteine

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. See section 4.

What is in this leaflet

1. What Carbocisteine is and what it is used for
2. What you need to know before you take Carbocisteine
3. How to take Carbocisteine
4. Possible side effects
5. How to store Carbocisteine
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1. What Carbocisteine is and what it is used for

Carbocisteine 375 mg Capsules, hard (called Carbocisteine in this leaflet) contains 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 is used for respiratory tract disorders 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 Carbocisteine if:

- you are allergic to carbocisteine or any of the other ingredients of this medicine (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.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine should not be taken during the first three months of your pregnancy.

3. How to take Carbocisteine

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

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.

Adults and elderly

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

Use in children

Carbocisteine is not recommended for children.

If you take more Carbocisteine than you should

If you take more 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 capsules, it is likely that you will get an upset stomach (gastrointestinal disturbance).

If you forget to take Carbocisteine

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 product, ask your doctor or pharmacist.

4. Possible side effects

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

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

- You have an allergic reaction. The signs may include: a rash, 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'.
- You have blood in your vomit or black tarry stools.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Vomiting.

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, website www.mhra.gov.uk/yellowcard.

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

5. How to store Carbocisteine

Store below 30°C.

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 carton and blister after "EXP". The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What Carbocisteine contains

- The active substance is carbocisteine. Each capsule contains 375 mg of carbocisteine.
- The other ingredients are:
Capsule Contents: mannitol; maize starch; croscarmellose sodium; sodium laurilsulfate, grade K12; colloidal anhydrous silica and magnesium stearate.
Capsule Shell: gelatine; red iron oxide E172; titanium dioxide E171 and yellow iron oxide E172.

What Carbocisteine looks like and contents of the pack

The Carbocisteine capsules are hard gelatine capsules, filled with homogenous white powder. The colour of the capsule body and of the capsule cap is dull-yellow opaque. The dimension of each capsule is approximately 19.4 ± 0.3 mm.

The capsules are blister-packed in transparent PVC/PVDC/aluminium hard foil. Each blister strip contains 10 capsules.

Pack sizes: 20, 30, 50 or 120 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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