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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 the sight and reach of children. Do not use this medicine after the expiry date which is stated on the packaging. 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 capsules contain

Each gelatin capsule contains 375 mg of the active substance, carbocisteine. The other ingredients are, lactose monohydrate, povidone, sodium laurilsulfate, magnesium stearate, gelatin, iron oxide yellow and titanium dioxide (E171).

See section 2 'Carbocisteine capsules contains lactose monohydrate and sodium laurilsulfate for further information.

What carbocisteine 375 mg capsules look like and the contents of the pack

Carbocisteine 375 mg Capsules are yellow and printed "C" on cap and "375" on body. 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

Key Pharmaceuticals Ltd.

Galen House, 83 High Street, Somersham, Cambridgeshire, PE28 3JB, UK

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in April 2024.

Package leaflet: information for the user Carbocisteine 375 mg Capsules, Hard

carbocisteine

Your medicine is called Carbocisteine 375 mg Capsules, Hard, but it will be referred to as carbocisteine capsules throughout this leaflet.

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 capsules are and what they are used for
2. What you need to know before you take carbocisteine capsules
3. How to take carbocisteine capsules
4. Possible side effects
5. How to store carbocisteine capsules
6. Contents of the pack and other information

1. What carbocisteine capsules are and what they are used for

Carbocisteine capsules 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 capsules

Do not take carbocisteine capsules

- If you are allergic (hypersensitive) 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

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breathing problems, swelling of the lips, face, throat or tongue

- If 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
- You have had an ulcer in your stomach or gut
- You are taking other medicines known to cause bleeding in the stomach

Children

This medicine is not recommended for use in children.

Other medicines and carbocisteine capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Carbocisteine capsules are not recommended during pregnancy or breast-feeding.

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant
- 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

Carbocisteine capsules are not known to affect the ability to drive or operate machinery.

Carbocisteine capsules contain lactose and sodium

Lactose

This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicinal product.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take carbocisteine capsules

Always take carbocisteine capsules exactly as your doctor has told you. You should 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

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 product, ask your doctor or pharmacist.

4. Possible side effects

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

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, 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:

- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea
- Stomach pain

Reporting 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


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Formatting Criteria	Carbocisteine 375mg Capsules-PIL
Single Page Dimensions	200 (W) x 200 (H)
Number of Pages	2 (Front/Back)
Font Style	Arial
Font Size – Headings	12 pt
Font Size – Sub headings	9 pt
Font Size – Body text	9 pt
Margins	Top/Bottom/Right/Left: 10 mm
Line-spacing	3.5 mm
Pictograms	NA

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