

Package leaflet: Information for the patient

Carbocisteine 250mg/5ml oral solution

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 oral solution is and what it is used for
2. What you need to know before you take Carbocisteine oral solution
3. How to take Carbocisteine oral solution
4. Possible side effects
5. How to store Carbocisteine oral solution
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1. WHAT CARBOCISTEINE ORAL SOLUTION IS AND WHAT IT IS USED FOR

Carbocisteine 250mg/5ml oral solution (called Carbocisteine oral solution in this leaflet) contains the active substance carbocisteine. This belongs to a group of medicines called "mucolytics". Mucolytics are used to treat mucus (phlegm) produced by infections of the breathing passages (respiratory tract) in adults and children 2 years and above. It works by making the mucus less sticky and easier to cough up.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CARBOCISTEINE ORAL SOLUTION

Do not take Carbocisteine oral solution:

- If you have an ulcer in your stomach or gut (small intestine).
- If you are allergic to carbocisteine or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Talk to your doctor before taking this medicine if:

- You are elderly.
- Have had an ulcer in your stomach or gut.

Children and adolescents

Do not give Carbocisteine oral solution to children younger than 2 years of age.

Other medicines and Carbocisteine oral solution

Tell your doctor if you are taking a medicine to treat a cough, as a productive cough is needed to remove mucus from your breathing passages.

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

Pregnancy and breastfeeding

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

Carbocisteine oral solution is not recommended during pregnancy or breastfeeding.

Fertility

The effects on fertility are unknown.

Driving and using machines

No effects were seen on the ability to drive and use machines.

Important information about some of the ingredients of Carbocisteine oral solution

This medicine contains:

- **Sodium:** 289.7mg (12.6mmol) of sodium per 45ml. This is equivalent to 14.4% of the recommended maximum daily dietary intake of sodium for an adult.
- **Sodium methyl parahydroxybenzoate:** it may cause allergic reactions (possible delayed), and exceptionally, bronchospasm.
- **Propylene glycol:** This medicine contains 0.8 mg propylene glycol in each millilitre, which is equivalent to 0.81 mg/ml

3. HOW TO TAKE CARBOCISTEINE ORAL SOLUTION

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

- For oral use only. Take this medicine by mouth.
- To give the correct dose use either a 15ml measuring cup or dosing syringe (marked in 0.25 ml quantities).
- Shake the bottle before use.

Adults including the elderly

The initial dose is 15ml (one measuring cup) three times a day; if symptoms improve, your doctor may lower your dose to 10ml, 3 times a day. The maximum daily dose is 45ml (3 measuring cups). Wash the measuring cup after use.

Children

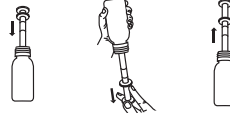
Children 2 - 5 years: The usual dose is 1.25 - 2.5 ml four times daily
Children 5 - 12 years: The usual dose is 5 ml three times daily.

Children under 2 years

Not recommended.

Using the dosing syringe

- When you use the medicine for the first time, place the adaptor in the neck of the bottle.
- Push the syringe firmly into the adaptor in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. Your doctor will tell you the right dose for your child.
- Turn the bottle the right way up, remove the syringe from the adaptor by gently twisting the syringe.



- Place the end of the syringe into the child's mouth and gently press the plunger down to slowly and gently release the medicine.
- After use replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of reach of children.

If you take more Carbocisteine than you should

- If you take more Carbocisteine oral solution than the label states or your doctor has prescribed, or if you think a child has accidentally swallowed any, contact the nearest hospital casualty department or a doctor for advice **immediately**.
- Take this leaflet with you

If you forget to take Carbocisteine oral solution

If you forget a dose, take the next dose as soon as you remember. Do not take a double 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 oral solution immediately and see a doctor or go to hospital straightaway if:

- You have an allergic reaction. Signs of an allergic reaction include: a rash, itching, problems swallowing or breathing, 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 have flu-like symptoms and fever. This is called "Stevens-Johnson syndrome".

Tell your doctor straight away if you notice any of the following serious side effects:

- You have blood in your vomit or black tarry stools. Your doctor may reduce your dose.

Other side effects are:

- Very common (may affect up to 1 in 10 people)**
- Stomach pains, feeling sick and diarrhoea.

- Uncommon (may affect up to 1 in 100 people)**
- Being sick

- Rare (may affect up to 1 in 1,000 people)**
- itching or a rash or swelling of the face.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 ORAL SOLUTION

Do not store above 25°C.

Keep this medicine out of the sight and reach of children.

Wash and dry the measuring cup and syringe after use.

Once opened use within one month.

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

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Carbocisteine contains

- Each 5ml of oral solution contains 250mg of the active substance, carbocisteine.

- The other ingredients are: glycerol, sodium saccharin, hydroxyethylcellulose, xanthan gum, caramel powder, raspberry flavour (contains propylene glycol E1520), sodium methyl parahydroxybenzoate (E219), sodium hydroxide, and purified water.

What Carbocisteine looks like and contents of the pack
Carbocisteine 250mg/5ml oral solution is a clear, amber-coloured liquid, with a raspberry odour.

Carbocisteine 250mg/5ml oral solution is packed in a 300ml glass bottle and comes with a 15ml measuring cup and a dosing syringe. The syringe is marked per 0.25ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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