



Carbocisteine 250mg/5ml sugar-free 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 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
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1 What Carbocisteine is and what it is used for

Carbocisteine 250mg/5ml Sugar-Free Oral Solution (called Carbocisteine Oral Solution in this leaflet) contains a medicine called Carbocisteine. This belongs to a group of medicines called “mucolytics” used in the therapy of respiratory tract disorders that are characterised by excessive and viscous (“sticky”) mucus. It works by making the mucus (catarrh) less sticky. This makes the mucus easier to exit when coughing.

2 What you need to know before you take Carbocisteine Oral Solution

Do not take Carbocisteine Oral Solution:

- If you have a gastroduodenal (stomach or gut) ulcer;
- 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 or pharmacist before taking Carbocisteine Oral Solution:

- Asthmatic patients and with a history of bronchial spasm (tightening of the airways muscles),
- Severe respiratory insufficiency,
- Debilitated patients. Due to the decrease of the cough reflex, there is risk of obstruction of the airway as a consequence of the increase of the quantity of secretions.

Children

This medicine is not indicated in children aged less than 2 years.

Other medicines and Carbocisteine Oral Solution

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

You should not take cough calming or secretion-drying medicines, because these have an effect contrary to that of Carbocisteine.

Pregnancy, breast-feeding and fertility

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.

Pregnancy:

It is not recommended for use in pregnant women, especially during the first trimester of pregnancy because the effects are not known.

Breast-feeding:

It is not recommended to use during breast-feeding because the effects are not known.

Driving and using machines

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

Carbocisteine Oral Solution contains Sodium methyl parahydroxybenzoate (E219).

May cause allergic reactions (possibly delayed).

Carbocisteine Oral Solution contains sodium

This medicine contains 12.7mg sodium per ml. It should be taken into account for those patients who are under a sodium-controlled diet.

3 How to take Carbocisteine Oral Solution

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Using the measuring device (oral measuring cup), measure the quantity that you will need whether you are an adult or a child, according to the general posology.

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

Use in adults including the elderly and adolescents over 12 years

The usual dose for adults is 15ml (one measuring cup) three times a day. If your symptoms improve, your dose may be lowered to 10ml three times a day. Wash the measuring cup after use.

Use in children and adolescents

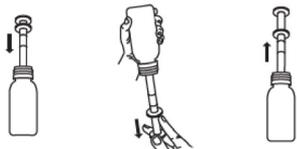
This medicine is not indicated in children aged less than 2 years.

From 2 to 5 years old: 1.25 - 2.5ml four times a day.

From 6 to 12 years old: 5ml three times a day in evenly spaced intervals. After using the oral solution, close the bottle well.

How to use the dosing syringe

- Place the syringe into the neck of the bottle below the fill line.
- 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 of the syringe.
- Turn the bottle the right way up, removing the syringe from the bottle.



- Place the end of the syringe into the mouth against the cheek 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 the reach of children.

If you take more Carbocisteine Oral Solution than you should

If upset stomach, nausea and vomiting occur, you should stop taking Carbocisteine and see the doctor.

If you forget to take Carbocisteine Oral Solution

If you forget to take a dose, do not worry, wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Carbocisteine Oral Solution

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

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

Uncommon:

Digestive changes: nausea, vomiting and diarrhoea.

Rare:

Hypersensitivity reactions, such as hives and bronchospasm (tightening of the airways muscles). Special attention in asthmatic patients due to the risk of occurring bronchoconstriction (contraction of a muscle of the bronchial wall that leads to a reduction in the air passage). In these cases, the treatment should be stopped. Headache, muscle pain, dizziness, involuntary urination (uncontrolled leakage of urine), palpitations and breathlessness.

Not known

Allergic reactions, such as skin rash. Special attention in patients with compromised thyroid function due to the risk of occurring hypothyroidism (underactive thyroid). Gastric discomfort (stomach pains), bronchorrhea (increased bronchial secretion).

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 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.

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

Once the bottle is opened, Carbocisteine must be used within 6 months.

If your oral solution appears to be discoloured or shown any other signs of deterioration, take it back to your pharmacist who will advise you.

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 Oral Solution contains

- The active substance is Carbocisteine. Each 5ml of Carbocisteine contains 250mg of Carbocisteine.
- The other ingredients are glycerol, Sodium methyl parahydroxybenzoate (E219), Saccharin sodium, Sodium hydroxide, Hydrochloric acid, Hydroxyethylcellulose, Strawberry Flavour, Caramel colourant and Purified water.

What Carbocisteine Oral Solution looks like and contents of the pack

Carbocisteine is presented as an amber liquid with strawberry flavour and a sweet taste.

It is in 300ml bottles, of type III amber glass with a child resistant screw cap, with a 15ml measuring device (oral measuring cup graduated to 2.5ml) and dosing syringe. The dosing syringe is marked per 0.25ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised
in **September 2021**