

Carbocisteine 250mg/5ml SYRUP

Carbocisteine

Amdeepcha

Package leaflet: Information for the user

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
6. Contents of the pack and other information

1. What Carbocisteine is and what it is used for

Carbocisteine 250 mg/5 ml syrup (called Carbocisteine in this leaflet) contains a medicine called carbocisteine. This belongs to a group of medicines called "mucolytics" used in the antibacterial treatment of respiratory infections, in the presence of bronchial hypersecretion. It works by making the mucus (catarrh) less sticky. This makes the mucus easier to exit when coughing. Carbocisteine syrup is used for problems in the airways when there is too much mucus or when it is too sticky.

2. What you need to know before you take Carbocisteine

Do not take Carbocisteine:

- if you have a gastroduodenal 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:

- Asthmatic patients and with a history of bronchospasm,
- 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.

The use of Carbocisteine implies a decrease of the mucus viscosity and its removal, either through the ciliary activity of the epithelium, either through the cough reflex, therefore an increase of the expectoration and cough should be expected. Do not associate this medicine with an antitussive. Mucolytics, as they have the ability to destroy the gastric mucosa barrier, should be used with caution in individuals susceptible to gastroduodenal ulcers.

Children

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

Other medicines and Carbocisteine

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 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.

Pregnancy:

It is not recommended to use in the pregnant woman, especially during the first 3 months of pregnancy, even though no teratogenic effects have been detected.

Breastfeeding:

It is not recommended to use during breastfeeding because there are no safety data, concerning the passage of carbocisteine into breast milk. Considering its low toxicity, if the mother is treated with this product, the potential risks for the child seem negligible.

Driving and using machines

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

Carbocisteine contains Sucrose

For use in children

This medicine contains 2.8 g of sucrose in each 5 ml paediatric dose. May be harmful to teeth. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

For use in adults

This medicine contains 8.4 g of sucrose in each 15 ml adult dose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Carbocisteine contains methyl parahydroxybenzoate.

May cause allergic reactions (possibly delayed).

3. How to take Carbocisteine

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 syringe with 5 ml capacity), measure the quantity that you will need whether you are an adult or a child, according to the general posology. The syringe for oral administration is graduated per 0.25 ml. One graduation, 0.25 ml corresponds to 12.5 mg of carbocisteine.

How to use the syringe:

Step 1: Check the measurements on the side of the syringe to see how much to fill it.

Step 2: Push the syringe's plunger all the way down. Then put the tip of the syringe into the medicine bottle.

Step 3: Slowly pull back on the plunger until the syringe fills to the appropriate mark.

Make sure there are not any large air bubbles in the syringe. If there are, empty the syringe and try again.

Step 4: Place the end of the syringe into the mouth against the cheek and carefully press the plunger down slowly to 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.

Use in adults

The usual dose for adults is 15 ml, 3 times daily. If your symptoms improve, your dose may be lowered to 10 ml, 3 times daily.

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 ml to 2.5 ml, 4 times daily.

From 6 to 12 years old: 5 ml, 3 times daily in evenly spaced intervals.

After using the syrup, close the bottle well.

If you take more Carbocisteine 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

If it is almost time to take the next dose, only take the next dose. If not, take the forgotten dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Carbocisteine

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, as hives and bronchospasm. Special attention in the 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, urinary incontinence, palpitations and breathlessness.

Not known

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

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

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

5. How to store Carbocisteine

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 3 months.

If your syrup 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 contains

- The active substance is carbocisteine. Each 5 ml of Carbocisteine contains 250 mg of carbocisteine.
- The other ingredients are: sucrose, caramel (E150), gooseberry flavour, sodium hydroxide (for pH-adjustment), methyl parahydroxybenzoate (E218) and purified water.

What Carbocisteine looks like and contents of the pack

Carbocisteine is presented as a yellow- amber liquid with gooseberry flavour and a sweet taste.

200 ml or 300 ml bottles, of type III amber glass, with measuring device (oral syringe with 5 ml capacity).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Amdeepcha Limited,
85 Yarmouth Road,
Blafield, Norwich,
Norfolk NR13 4LQ, United Kingdom

Manufacturer

Laboratórios Basi – Indústria Farmacêutica, S.A.
Parque Industrial Manuel Lourenço Ferreira, Lotes 8, 15 e 16
3450-232 Mortágua, Portugal
Tel.: +351 231 920 250
Fax: +351 231 921 055
E-mail: basi@basi.pt

This leaflet was last revised in November 2019

Marketing