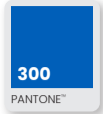



Product name: Esteve - Carbocisteine 750/10ml Artwork origination: 29/09/22 Last Modified: 03/10/22 Dimemions (mm): 200(W) x 280(H) Typefaces: Dax Bold and Dax Regular Minimum Type Size: 10pt	Printed Colours: 	Non Printed 
--	---	--

20



datamatrix control code
= plant packaging code
+ Quiet area for datamatrix

Package leaflet: Information for the user

Carbocisteine

750mg/10ml sugar-free oral solution in sachet

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.

What is in this leaflet

1. What Carbocisteine oral solution in sachet is and what it is used for
2. What you need to know before you take Carbocisteine oral solution in sachet
3. How to take Carbocisteine oral solution in sachet
4. Possible side effects
5. How to store Carbocisteine oral solution in sachet
6. Contents of the pack and other information

1. What Carbocisteine oral solution in sachet is and what it is used for

This medicine belongs to a group of medicines called "mucolytics". It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up. This medicine is used for problems with the breathing passages (respiratory tract).

This medicine is indicated in adults and children over 15 years.

2. What you need to know before you take Carbocisteine oral solution in sachet

Do not take Carbocisteine oral solution in sachet:

- if you are allergic to carbocisteine or any of the other ingredients contained in Carbocisteine oral solution in sachet,
- if you have an ulcer in your stomach or gut (small intestine).

When in doubt, you should always consult a doctor or pharmacist.

Please take special care with Carbocisteine oral solution in sachet:

Consult your doctor immediately:

- if you have thick, purulent sputum or fever,
- if you suffer from chronic illness (long-term) of the bronchi or lungs,
- if you are elderly,
- if you have had an ulcer in your stomach or gut,
- if you are taking other medicines known to cause bleeding in the gut.

Precautions for use

This medicine should always be accompanied by voluntary efforts to cough, which help expectoration.

Do not take cough medicine (to stop coughing) or medicine that dries out bronchial secretions during the treatment period with carbocisteine.

CONSULT A DOCTOR IF NO IMPROVEMENT IS SEEN.

Other medicines and Carbocisteine oral solution in sachet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even if it is medication obtained without a prescription.

This medicine contains carbocisteine. Other medications also contain carbocisteine. Please do not take them at the same time in order to avoid exceeding the maximum doses advised (see 3. HOW TO TAKE Carbocisteine oral solution in sachet)

Pregnancy and breast-feeding

Carbocisteine is 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.

Important information about some of the ingredients in Carbocisteine oral solution in sachet:

This medicine contains the following excipients with known effects:

- Sodium
- Sodium methyl para-hydroxybenzoate (E 219)
- Maltitol
- Sorbitol
- Ethanol (alcohol, present in caramel/vanilla flavouring)

This medicine contains sodium. This medicine contains 97.5 mg (4.24 mmol) of sodium per sachet. This should be taken into account in patients following strict low sodium diets.

This medicine contains sodium methyl para-hydroxybenzoate and can cause allergic reactions.

This medicine contains maltitol and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

XXXXXX

ULM packaging code

This medicine contains small quantities of ethanol (alcohol), less than 100 mg per sachet.

When in doubt, please ask your doctor or pharmacist.

3. How to take Carbocisteine oral solution in sachet

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

Mode of administration

Oral route.

FOR ADULTS AND CHILDREN OVER 15 YEARS ONLY

Do not use this medicine in children under 15 years.

Posology

The standard dose is 750 mg of carbocisteine 3 times a day, or one 10 ml sachet 3 times a day.

If your symptoms improve, your dose may be lowered to 2 sachets per day (taken separately). This medicine is appropriate for patients following a low sugar or low calorie diet.

If you feel that the effects of Carbocisteine oral solution in sachet are too strong or not strong enough, please talk to your doctor or pharmacist.

If symptoms (cough) persist, consult your doctor.

If you take more Carbocisteine oral solution in sachet than you should:

Contact your 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 much, it is likely that you will get an upset stomach (gastrointestinal disturbance).

If you forget to take Carbocisteine oral solution in sachet:

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, Carbocisteine oral solution in sachet can cause side effects, although not everybody gets them.

Stop taking Carbocisteine oral solution 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 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 in sachet

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. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 in sachet contains

The active substance is carbocisteine. Each 10 ml oral solution contains 750 mg of carbocisteine.

The other ingredients are:

Saccharin sodium, sodium methyl para-hydroxybenzoate (E 219), hydroxyethylcellulose, caramel/vanilla flavouring (contains alcohol), sorbitol liquid (non-crystallising), maltitol liquid, sodium hydroxide*, purified water.

* sodium hydroxide pellets or sodium hydroxide 30 % solution

What Carbocisteine oral solution in sachet looks like and contents of the sachet

This medicine is available in 10 ml sachets and comes in boxes of 10, 12 or 15 sachets. It is a limpid, viscous, light brown solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Esteve Pharmaceuticals Ltd,
The Courtyard Barns,
Choke Lane, Cookham Dean,
Maidenhead, Berks. SL6 6PT,
United Kingdom

Manufacturer

UNITHER LIQUID MANUFACTURING
1-3 allée de la Neste
ZI d'En Sigal
31770 COLOMIERS

This leaflet was last revised in September 2022.

Detailed information on this medicine is available on the web site of UK Medicines and Healthcare products Regulatory Agency (www.mhra.gov.uk/).



Quiet area in backing of datamatrix on the first page