Package Leaflet: Information for the user

Carbocisteine 250 mg/5 ml Adult Syrup 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.

The full name of this product is Carbocisteine 250 mg/5 ml Adult Syrup but within the leaflet it will be referred to as Carbocisteine 250 mg/5 ml Syrup.

What is in this leaflet:

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

1. What Carbocisteine Syrup is and what it is used for

Carbocisteine 250 mg/5 ml Syrup (called Carbocisteine Syrup in this leaflet) contains a medicine called Carbocisteine. This belongs to a group of medicines called 'mucolytics'.

Carbocisteine Syrup is used for problems with the breathing passages (respiratory tract) caused by too much sticky mucus. Carbocisteine works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up.

2. What you need to know before you take Carbocisteine Syrup

Do not take Carbocisteine Syrup:

- If you are allergic (hypersensitive) to carbocisteine or any of the other ingredients of Carbocisteine Syrup (listed in section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- If you have an ulcer in your stomach or gut (small intestine).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Carbocisteine Syrup.

Warnings and precautions

Talk to your doctor before taking Carbocisteine Syrup if:

- You are elderly.
- Have had an ulcer in your stomach or gut.
- You are taking other medicines known to cause bleeding in the stomach.
- This medicine is not recommended for use in children and adolescents under the age of 18 years due to the alcohol content.

This medicine can cause a mild laxative effect due to the content of maltitol liquid.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant. This medicine should not be taken during the first three months of your pregnancy.
- 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 of Carbocisteine Syrup

Carbocisteine Syrup contains:

- **Liquid Maltitol:** If you have been told by the doctor that you cannot tolerate some sugars, talk to your doctor before taking Carbocisteine Syrup
- **Ethanol:** Carbocisteine Syrup contains approximately 11.9 % ethanol (alcohol). A 15ml dose of this medicine contains up to 1.5 g of ethanol; this is about the same amount of alcohol as 35.6ml of beer or 14.8ml of wine (i.e. 1/10 glass of wine) per dose. This can be harmful for those suffering from alcoholism. It should also be taken into account in pregnant or breast-feeding women and high risk groups such as patients with liver disease or fits (epilepsy).
- **Sodium:** This medicine contains 99mg of sodium in each 15ml dose. Take this into consideration if you are on a controlled sodium diet

3. How to take Carbocisteine Syrup

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

Taking this medicine

- Take this medicine by mouth
- Carbocisteine Syrup comes with a measuring beaker

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 15ml three times each day
- If your symptoms improve, your dose may be lowered to 10ml, three times, each day

Children

Carbocisteine Syrup is not recommended for children.

This medicine is not recommended for use in children and adolescents under the age of 18 years due to the alcohol content.

If you take more Carbocisteine Syrup than you should

If you take more Carbocisteine Syrup 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 much Carbocisteine Syrup, it is likely that you will get an upset stomach (gastrointestinal disturbance).

If you forget to take Carbocisteine Syrup

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 medicine, 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 Syrup 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'

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

- 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:

- Vomiting

Talk to your doctor or a pharmacist if you notice any side effects not listed in this leaflet.

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 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 Syrup

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 label and carton after EXP. The expiry date refers to the last day of that month.

After use, wipe the neck of the bottle with a clean, damp cloth. This will remove any medicine left on the bottle, so you can put the cap back on tight. If you use the measuring beaker to take this medicine, make sure the beaker is clean and dry before you use it.

Do not store above 25 °C. Store in the original container and keep the bottle in the outer carton to protect from light.

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 Syrup contains

- Each 5ml of syrup contains 250mg of the active substance, carbocisteine
- The other ingredients are Xanthan gum, sodium saccharin, liquid maltitol, 96% ethanol, sodium hydroxide, caramel flavouring agent*, purified water.

* Composition of caramel flavouring agent IFF SC227828 : diacetyl, propylene glycol, butyric acid, methylcyclopentenolone, maltol, 4-hydroxy-2,5-dimethyl-3(2H)-furanone, piperonal and vanillin.

What Carbocisteine Syrup looks like and contents of the pack

Carbocisteine Syrup is clear pale yellow syrup with caramel odour sweetened with saccharin sodium and liquid maltitol.
Carbocisteine Syrup is available in bottles of 200 ml, 250 ml or 300 ml comes with a measuring beaker.

Marketing Authorisation Holder and Manufacturer

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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 02/2019