PACKAGE LEAFLET

Package leaflet: Information for the user

Carbocisteine 750mg/5ml sugar-free 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Carbocisteine sugar-free syrup is and what it is used for
- 2. What you need to know before you take Carbocisteine sugar-free syrup
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1. What Carbocisteine sugar-free syrup is and what it is used for

Carbocisteine 750mg/5ml sugar-free syrup contains the active substance carbocisteine. This belongs to a group of medicines called "mucolytics".

It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up.

Carbocisteine sugar-free syrup is used to treat mucus produced by infections of the breathing passages (respiratory tract) in adults and children from 15 years of age.

Carbocisteine is used for problems with the breathing passages. These problems happen when too much mucus is made or the mucus is too sticky.

2. What you need to know before you take Carbocisteine sugar-free syrup

Do not take Carbocisteine sugar-free syrup:

- 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 Carbocisteine sugar-free syrup:

- 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 stomach.

Children and adolescents

Do not give Carbocisteine sugar-free syrup to children younger than 15 years of age.

Other medicines and Carbocisteine sugar-free syrup

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

• Any medicines to treat a cough as a productive cough is necessary to remove mucus from your breathing passages.

Pregnancy and breast-feeding

Carbocisteine Syrup is not recommended during pregnancy, especially during the first three months of your pregnancy.

The use of Carbocisteine Syrup in breast-feeding women is not recommended. The effects of carbocisteine on a breastfed infant are not known, and it is not known whether carbocisteine is present in human milk.

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.

Driving and using machines

Carbocisteine Syrup will have little or no influence on your ability to drive or use machines.

Carbocisteine sugar-free syrup contains sodium

This medicine contains 288.4mg of sodium (main component of cooking/table salt) in each 15ml dose. This is equivalent to 14.4% of the recommended maximum daily dietary intake of sodium for an adult.

Carbocisteine sugar-free syrup contains sodium methyl parahydroxybenzoate

This medicine contains sodium methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

3. How to take Carbocisteine sugar-free 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.

- For oral use only.
- Use the measuring cup provided (marked with 2.5/5ml graduations).
- Shake the bottle before use.

Adults including the elderly and children from 15 years of age

The initial dose is 5ml three times a day; if symptoms improve, your doctor may lower your dose to 5ml, two times a day. The maximum daily dose is 15ml.

Children under 15 years of age

Not recommended.

If you take more Carbocisteine sugar-free syrup than you should

- If you take more Carbocisteine sugar-free syrup than the label states or your doctor has prescribed, or if you think a child has accidently swallowed any, contact the nearest hospital casualty department or a doctor for advice **immediately**. Take the medicine pack and this leaflet with you.
- If you take too much Carbocisteine sugar-free syrup you may get an upset stomach (gastrointestinal disturbance).

If you forget to take Carbocisteine sugar-free syrup

If you forget a dose, take the next dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

Check the dose carefully

The amount of syrup needed to provide the required dose is less than for other carbocisteine products.

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 sugar-free syrup immediately and see a doctor or go to hospital straight away if:

- You have an allergic reaction. Signs of an allergic reaction include: a rash, 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 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).
- 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 sugar-free syrup

Do not store above 25°C.

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

Wash and dry the measuring cup 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 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 sugar-free syrup contains

- Each 5ml of oral solution contains 750mg of the active substance carbocisteine.
- The other ingredients are glycerol, sodium saccharin, hydroxyethylcellulose, xanthan gum, caramel powder, raspberry flavour, sodium methyl parahydroxybenzoate, sodium hydroxide, and purified water.

What Carbocisteine sugar-free syrup looks like and contents of the pack

Carbocisteine 750mg/5ml sugar-free syrup is clear, amber-coloured liquid, with a raspberry odour.

Carbocisteine 750mg/5ml sugar-free syrup is packed in 100ml or 200ml glass bottle and comes with a measuring cup with 2.5/5ml graduations.

Marketing Authorisation Holder

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