

Package leaflet: Information for the user**Carbocisteine 375 mg Hard Capsules**

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 375mg capsules are and what they are used for
2. What you need to know before you take Carbocisteine 375mg capsules
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1. What Carbocisteine 375mg capsules are and what they are used for

Carbocisteine 375mg capsules contain a medicine called 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 375mg capsules are used for problems with the breathing passages (respiratory tract). 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 375mg capsules**Do not take Carbocisteine 375mg capsules:**

- If you are allergic to carbocisteine or to any of the other ingredients of this medicine (listed in section 6).
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.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Carbocisteine 375mg capsules.

Children

Carbocisteine 375mg capsules are not recommended for children.

Other medicines and Carbocisteine 375mg capsules

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

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

This medicine should not be taken during the first three months of your pregnancy.

Driving and using machines

No effects on the ability to drive or use machines have been seen with carbocisteine.

3. How to take Carbocisteine 375mg capsules

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.
- 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 two capsules, 3 times each day.
- If your symptoms improve, your dose should be lowered to one capsule, 4 times each day.

Use in Children

- Carbocisteine 375mg capsules are not recommended for children.

If you take more Carbocisteine 375mg capsules than you should

If you take more Carbocisteine 375mg capsules 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 many Carbocisteine 375mg capsules, it is likely that you will get an upset stomach (gastrointestinal disturbance).

If you forget to take Carbocisteine 375mg capsules

If you forget to take 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 375mg capsules 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:

- 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 (being sick)

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 to HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbocisteine 375mg capsules

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

Store below 30°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 to protect the environment.

6. Contents of the pack and other information

What Carbocisteine 375mg capsules contain

- Each capsule contains 375 mg of the active substance, carbocisteine.

- The other ingredients are maize starch, pregelatinised maize starch and magnesium stearate. The capsule shell contains titanium dioxide (E171), yellow iron oxide (E172) and gelatin.

What Carbocisteine 375mg capsules look like and contents of the pack

Carbocisteine 375mg capsules are yellow, size 0 hard capsules containing a white to off white powder. They are available in blister packs containing 6, 18, 30 or 120 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

Chanelle Medical, Loughrea, Co. Galway, Ireland.

Manufacturer

Chanelle Medical, Loughrea, Co. Galway, Ireland.

JSC Grindeks, 53 Krustpils street, Riga, LV-1057, Latvia.

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.

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