

PACKAGE LEAFLET: INFORMATION FOR THE USER

Carbocisteine Teva 375 mg capsules, hard

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Carbocisteine Teva is and what it is used for
2. Before you take Carbocisteine Teva
3. How to take Carbocisteine Teva
4. Possible side effects
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1. WHAT CARBOCISTEINE TEVA IS AND WHAT IT IS USED FOR

Carbocisteine Teva 375 mg capsules, hard (called Carbocisteine Teva in this leaflet) contain a medicine called carbocisteine. This belongs to a group of medicines called 'mucoytics'. It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up. Carbocisteine Teva is 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. BEFORE YOU TAKE CARBOCISTEINE TEVA

DO NOT take Carbocisteine Teva if you

- **are allergic (hypersensitive) to** carbocisteine or any of the other ingredients of Carbocisteine Teva (see list of ingredients in section 6). An allergic reaction may include rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- **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 Teva.

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 Teva

Patients who are intolerant to **lactose** (milk sugar) should note that Carbocisteine Teva contains a small amount of **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE CARBOCISTEINE TEVA

Always take Carbocisteine Teva exactly as your doctor has told you. You should 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

Children

Carbocisteine Teva is not recommended for children.

If you take more Carbocisteine Teva than you should

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

If you forget to take Carbocisteine Teva

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Carbocisteine Teva can cause side effects, although not everybody gets them.

Stop taking Carbocisteine Teva and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- An allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing, severe skin rash or hives.
- Blood in your vomit or black tarry stools.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

Rare (affecting less than one person in 1,000 but more than one person in 10,000):

- Nausea, diarrhoea.

Very rare (affecting less than one person in 10,000):

- Allergic skin reactions such as pruritus, urticaria and rash
- Abdominal pain.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CARBOCISTEINE TEVA

Keep out of the reach and sight of children.
Do not store above 25°C.

Do not use Carbocisteine Teva after the expiry date which is stated on the blister and carton or label after the abbreviation EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Carbocisteine Teva contains

The active substance is carbocisteine. Each Carbocisteine Teva capsule contains 375 mg carbocisteine.

The other ingredients are:

Lactose monohydrate

Sodium laurilsulphate

Silica, colloidal anhydrous

Magnesium stearate

Capsule cap/body:

Gelatin

Sodium laurilsulphate

Iron oxide yellow (E172)

Titanium dioxide (E171)

Printingink:

Shellac, Black iron oxide (E172), Propylene glycol, Potassium hydroxide

What Carbocisteine Teva looks like and contents of the pack

Carbocisteine Teva capsules are yellow, size 1 hard capsules, imprinted “6C1” on the cap and “375” on the body, containing a white or off-white granular powder. They are available in tubs containing 100 capsules, or in blister packs of 30, 100 & 120 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom.

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: Carbocisteine 375 mg capsules, hard

Ireland: Carbocisteine Teva 375 mg capsules, hard

This leaflet was last approved in March 2013