

Package leaflet: Information for the patient

Acetylcysteine 200 mg Powder for Oral Solution

Acetylcysteine

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, pharmacist or nurse.
- 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

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2. What you need to know before you take Acetylcysteine 200 mg Powder
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1. What Acetylcysteine 200 mg Powder is and what it is used for

This medicine is called Acetylcysteine 200 mg Powder for Oral Solution (referred to as Acetylcysteine 200 mg Powder throughout this leaflet). Each sachet contains the active substance acetylcysteine. Acetylcysteine belongs to a group of medicines called mucolytics which work by thinning the mucus (phlegm) so that it can be coughed up more easily.

Acetylcysteine 200 mg Powder is used to treat:

- breathing difficulties caused by too much mucus in the lungs and airways or the mucus being too thick and sticky to cough up easily.

2. What you need to know before you take Acetylcysteine 200 mg Powder

Do not take Acetylcysteine 200 mg Powder:

- if you are **allergic** (hypersensitive) to acetylcysteine, other similar medicines (such as carbocisteine, erdosteine or mecysteine), or any of the other ingredients of this medicine (listed in section 6).
- if you have a genetic condition called **phenylketonuria** where you are unable to break down a substance called phenylalanine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Acetylcysteine 200 mg Powder:

- if you suffer from **asthma, as you may need to be monitored closely whilst taking this medicine**
- if, before you start taking this medicine, you have a **reduced ability or inability to cough**, then it may be necessary to remove the mucus by suction after this medicine has loosened it
- if you are due to have any blood or urine tests, as acetylcysteine can interfere with some laboratory tests.

Acetylcysteine 200 mg Powder On opening the sachet, Acetylcysteine 200 mg Powder may **smell of sulphur (rotten eggs)**. This is a normal characteristic of this medicine and does not mean that it is not safe to use. Upon addition of water the solution will have a citrus odour.

Children and adolescents

Do not use in children under the age of 12 years.

Other medicines and Acetylcysteine 200 mg Powder

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines which you have bought without a prescription.

You must **tell your doctor or pharmacist** if you are taking any of the following medicines:

- medicines to treat **coughs** (e.g. cough syrup)
- **activated charcoal**, used to treat poisoning
- drugs used to treat bacterial infections, **antibiotics** (e.g. cefalexin, cefuroxime, cefadroxil, cefaclor, ceftriaxone). This medicine can prevent some antibiotics from working properly if they are taken at the same time as it. If you have been told this applies to you, you should **take this medicine either two hours before or two hours after taking your antibiotics**. If you are not sure if this applies to you, talk to your doctor or pharmacist.
- medicines to treat **angina** attacks, (tightness in your chest, neck and arm) (e.g. **glyceryl trinitrate**)

Acetylcysteine 200 mg Powder with food, drink and alcohol

There are no special requirements to consider when taking this medicine with food, drink or alcohol.

Pregnancy and breast-feeding

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

Acetylcysteine 200 mg Powder should not affect your ability to drive or operate machinery. If you experience side effects which may affect these abilities, do not drive or operate machinery until the effects have completely disappeared.

Acetylcysteine 200 mg Powder contains sorbitol, aspartame and sunset yellow

- **If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.**
- Aspartame is a source of phenylalanine. Phenylalanine can be harmful to people with a condition called phenylketonuria.
- **Sunset yellow (a food colouring) may cause allergic reactions.**

3. How to take Acetylcysteine 200 mg Powder

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

Adults and adolescents over the age of 12 years

The recommended dose is 1 sachet 3 times a day, or as prescribed by your doctor.

Directions for use

Empty the sachet contents into a small amount of **water** in a glass and **stir** until it dissolves (mixes) completely, just before drinking. It is important to **drink all** of the mixture.

Abundant fluid intake supports the mucolytic effect of acetylcysteine.

If you take more Acetylcysteine 200 mg Powder than you should

If you accidentally **take more** Acetylcysteine 200 mg Powder than you have been prescribed, **contact your doctor or get medical advice immediately**. If possible, take the sachets, the box and this leaflet with you to show the doctor.

The following are all symptoms of an overdose:

- Feeling or being sick and diarrhoea.

If you forget to take Acetylcysteine 200 mg Powder

If you forget to take a dose, take it as soon as possible. Take the next dose at the correct time, in accordance with the instructions given by your doctor. However, if it is almost time to take the next dose, do not take the dose you have missed; only take the next dose as normal.

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

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

4. Possible side effects

Like all medicines, Acetylcysteine 200 mg Powder can cause side effects, although not everybody gets them.

Stop taking Acetylcysteine 200 mg Powder and get medical advice straight away if you experience any of these very rare side effects (affecting less than 1 in 10,000 people):

- **severe, life-threatening allergic reaction.** The signs may include: a **rash**, swallowing or breathing problems, **swelling of your lips, face, throat or tongue**
- **severe bleeding** (haemorrhaging)
- **blistering, peeling, bleeding, scaling, or fluid filled patches** on any part of your **skin**. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may have a serious skin problem.

Tell your doctor or pharmacist if any of the following side effects become serious or last longer than a few days:

Uncommon side effects

(affecting less than 1 in 100 people)

- Headache
- A ringing sound in the ears (tinnitus)
- A fast heart rate
- Feeling or being sick
- Diarrhoea
- Inflammation of the skin in your mouth and on your lips
- Pain in your abdomen (tummy)
- An itchy raised rash
- Swelling of the deeper layers of skin, caused by a build up of fluid
- Itchy skin
- Fever
- Low blood pressure, this could cause dizziness when standing up quickly from a lying/seated position

Rare side effects

(affecting less than 1 in 1,000 people)

- Tightness of your airways
- Shortness of breath
- Indigestion

Not known

(this means the frequency cannot be estimated from the information available)

- Swelling of the face

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 to the relevant medicines authority (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

The Yellow Card Scheme
Medicines and Healthcare Products Regulatory Agency
151 Buckingham Palace Road

Victoria, London, SW1W 9SZ,
United Kingdom
Website:
www.yellowcard.mhra.gov.uk

5. How to store Acetylcysteine 200 mg Powder

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

Store in the original package to protect from moisture.

Once the contents of the sachet have been dissolved in water use this medicinal product immediately. Do not store the solution.

Do not use this medicine after the expiry date which is stated on the sachet and 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 Acetylcysteine 200 mg Powder contains

- The active substance is acetylcysteine.
Each sachet contains 200 mg acetylcysteine.
- The other ingredients (excipients) are aspartame, sorbitol, lemon flavour (contains maltodextrin, a form of glucose) and sunset yellow.

What Acetylcysteine 200 mg Powder looks like and contents of the pack

Acetylcysteine 200 mg Powder is a white to slightly pink coloured powder.

Acetylcysteine 200 mg Powder is available in boxes of 10, 18, 20 or 30 sachets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Colonis Pharma Limited
25 Bedford Square
Bloomsbury
London
WC1B 3HH
United Kingdom

Manufacturer

Lamp San Prospero S.p.A.
Via della Pace 25/A
41030, San Prospero (MO)
Italy

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