

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

The name of your medicine is Acetylcysteine 200 mg Powder for Oral Solution (referred to as Acetylcysteine 200 mg Powder in this leaflet).

Each sachet contains the active substance acetylcysteine. Acetylcysteine belongs to the group of medicines called mucolytics which work by thinning the mucus (phlegm) so that it can be coughed up more easily.

This medication 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, for adults and adolescents from 12 years of age.

You should consult a doctor if it gets worse or does not improve after 5 days.

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 carbocysteine, erdosteine or mecysteine) or any of the other ingredients of this medicine listed in section 6.
- if you have a stomach or duodenal ulcer.
- Do not administer to children under 2 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before you take 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.

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 it is not safe to use.

Children and adolescents

Children between 2 and 12 years of age should not take this medicine.

There are other presentations more suitable for this population.

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 medicines obtained 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) or with those that decrease bronchial secretions (such as antihistamines and anticholinergics), as they may cause an accumulation of liquified mucus.
- **activated charcoal**, used to treat poisoning.
- medicines used to treat bacterial infections, **antibiotics** (e.g. cefalexin, cefuroxime, cefadroxil, cefaclor, ceftriaxone), amphotericin B, ampicillin sodium, cephalosporins, erythromycin lactobionate and some tetracyclines. This medicine can prevent some antibiotics from working properly if they are taken at the same time as it. **If you have been told that 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**).
- if you are taking any medicine that contains minerals such as iron or calcium.
- co-administration with the antiepileptic carbamazepine may result in decreased efficacy of carbamazepine.

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, breast-feeding and fertility

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.

As a precautionary measure, it is preferable to avoid its use during pregnancy.

It should be avoided during breastfeeding.

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 sucrose and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

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 taken three times a day, or as prescribed by your doctor.

Directions for use

Empty the contents of one sachet into a glass containing **150 ml of water** and **stir** using a teaspoon until it dissolves completely (within 5 minutes). It is important to **drink all** of the mixture immediately. Do not store the solution.

Drink plenty of liquids. Staying hydrated supports the mucolytic (mucus thinning) effect of acetylcysteine.

You should consult a doctor if your condition gets worse or does not improve after 5 days of treatment.

Use in children

Children under 12 years of age cannot take this medicine.

There are other presentations more suitable for this population.

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 signs of overdose:

- nausea (feeling sick), vomiting (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 the missed 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 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)

- Drowsiness
- Tightness of your airways
- Shortness of breath
- Indigestion

Not known (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 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 Acetylcysteine 200 mg Powder

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

Store in a cool, dry place and protect from light. Keep the sachets in the outer carton. This medicinal product does not require any special temperature storage conditions.

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 carton and sachet 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 3 g sachet contains 200 mg of acetylcysteine.

The other ingredients are sucrose, ascorbic acid, saccharin sodium, and Orange flavour DM6024 (natural & nature identical & synthetic flavoring ingredients, lactose).

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

White to off white granular powder, after reconstitution in water forms a clear and colourless solution. Acetylcysteine 200 mg Powder is available as 4 ply laminate paper foil sachets containing 3 g powder for oral solution, 30 sachets in a carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

Manufacturer

Waymade PLC, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

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