

Package leaflet: Information for the patient

Acetylcysteine 200 mg Powder for Oral Solution

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PRODOTTO	-	Acetylcysteine 200 mg
CODICE	-	1693/A
DATA	-	29/08/2018
RESP.	-	Damiano

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
Quantum House
Hobson Industrial Estate
Burnopfield
County Durham
NE16 6EA
United Kingdom

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

This leaflet was last revised in July 2018