

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

ACETYLCYSTEINE 200 ADCO (effervescent tablet)

Acetylcysteine 200 mg

ACETYLCYSTEINE 600 ADCO (effervescent tablet)

Acetylcysteine 600 mg

Contains sweetener: sodium saccharin 20 mg.

Read all of this leaflet carefully because it contains important information for you:

ACETYLCYSTEINE ADCO is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ACETYLCYSTEINE ADCO carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACETYLCYSTEINE ADCO with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- ACETYLCYSTEINE ADCO should not be taken for more than 14 days without medical advice.

What is in this leaflet:

1. What ACETYLCYSTEINE ADCO is and what it is used for.
2. What you need to know before you take ACETYLCYSTEINE ADCO
3. How to take ACETYLCYSTEINE ADCO
4. Possible side effects

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5. How to store ACETYLCYSTEINE ADCO
6. Contents of the pack and other information

1. What ACETYLCYSTEINE ADCO is and what it is used for:

ACETYLCYSTEINE ADCO is used to help thin and loosen mucus in the lungs during transient (i.e., short-term) breathing problems like chest congestion or a cough.

2. What you need to know before you take ACETYLCYSTEINE ADCO

Do not take/give ACETYLCYSTEINE ADCO, If you have/are:

- If you are allergic to the active substances or to any of the excipients listed.
(Listed in section 6)
- Pregnant or breastfeeding
- Active peptic ulceration (open sores in the upper part of the digestive tract)
- Children below 2 years of age

Warnings and Precautions

Take special care with ACETYLCYSTEINE ADCO:

- Patients with bronchial asthma (a condition in which a person's airways become inflamed, narrow and swell and produce extra mucus, which makes it difficult to breathe) should be closely monitored during therapy. If tightening of the lung muscles, causing restricted flow occurs, treatment should be discontinued immediately and appropriate treatment started.
- Mucolytics (medicines that make mucus less thick and sticky and easier to cough up) can cause airways obstruction in children under 2 years of age.
This is due to their lungs not being fully developed yet.

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- The use in patients affected by stomach ulcers or with a history thereof requires special attention, especially when taking other medicines that could negatively affect the stomach.
- If the patient is unable to cough out or spit out phlegm effectively, in order to avoid a build-up of phlegm, it is necessary to employ postural drainage (a method for clearing the lungs by changing position) and broncho aspiration (the act of inhaling fluid or a foreign body into the bronchi and lungs, often after vomiting).
- ACETYLCYSTEINE ADCO can affect the substance histamine that is released from some types of white blood cells during allergic reactions. Therefore, caution should be used when administering ACETYLCYSTEINE ADCO to patients with histamine intolerance, as doing so may lead to symptoms of hypersensitivity.
- The occurrence of severe skin reactions such as Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals) and Lyell's syndrome (life-threatening reaction with flu-like effects and blistering in the skin, mouth eyes and genitals) has very rarely been reported in connection with the use of acetylcysteine. If skin and mucosal (Thin skin inside surface of parts of the body) changes occur, the use of ACETYLCYSTEINE ADCO must be stopped immediately. (see section 4).

Other medicines and ACETYLCYSTEINE ADCO:

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

- It is advisable not to mix other medicines with the ACETYLCYSTEINE ADCO mucolytic solution.
- Using ACETYLCYSTEINE ADCO together with *cough suppressants* may cause a dangerous secretory congestion due to the reduced cough reflex, so that an especially careful diagnosis is required for this combination treatment.

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- *Tetracycline hydrochlorides* (excluding doxycycline) and other *oral antibiotics* must be used separately from ACETYLCYSTEINE ADCO and with an interval of at least 2 hours.
- If using together with *glyceryl trinitrate* (medicine used to treat chest pain) and ACETYLCYSTEINE ADCO, patients should be monitored for the possible development of low blood pressure, which can be serious, and can cause headaches.
- *Activated charcoal* in high doses (as an antidote) can reduce the effects of ACETYLCYSTEINE ADCO.

Pregnancy, breastfeeding & fertility:

Safety and efficacy of ACETYLCYSTEINE ADCO in pregnancy and lactation have not been established.

No fertility data available. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ACETYLCYSTEINE ADCO.

Driving and using machines:

ACETYLCYSTEINE ADCO's effect on the ability to drive and use of machines is not established. It is not always possible to predict to what extent ACETYLCYSTEINE ADCO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ACETYLCYSTEINE ADCO affects them.

3. How to take ACETYLCYSTEINE ADCO

Do not share medicines prescribed for you with any other person.

Always use ACETYLCYSTEINE ADCO exactly as described in this leaflet or as your health care professional has told you. Check with your health care professional if you are not sure.

The usual dose is:

ACETYLCYSTEINE 200 ADCO:

Children from 2-5 years of age: ½ (half) an effervescent tablet 2 to 3 times a day.
(equivalent to 200 to 300 mg acetylcysteine/day).

Children from 6-14 years of age: 1 effervescent tablet twice daily (equivalent to 400 mg acetylcysteine/day).

Adults & adolescents from 14 years of age: 1 effervescent tablet 2 to 3 times daily
(equivalent to 400 to 600 mg acetylcysteine/day).

ACETYLCYSTEINE 600 ADCO:

Adults & adolescents from 14 years of age: 1 effervescent tablet daily, or ½ effervescent tablet twice daily (equivalent to 600 mg acetylcysteine per day).

Do not exceed the recommended dosage.

Method of administration: The effervescent tablets are taken dissolved in a glass of water before use after meals.

Duration of use: Do not use continuously for more than 14 days without medical advice.

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If you take more ACETYLCYSTEINE ADCO than you should:

Side effects will be precipitated or be of increased severity. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

Overdose can cause gastrointestinal symptoms such as nausea, vomiting and diarrhoea. Treatment of overdose is supportive and symptomatic.

If you forget to take ACETYLCYSTEINE ADCO:

Take your next dose at your regular time.

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

4. Possible Side Effects

ACETYLCYSTEINE ADCO can have side effects.

Not all side effects reported for ACETYLCYSTEINE ADCO are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ACETYLCYSTEINE ADCO, please consult your health care provider for advice.

If any of the following happens, stop taking / using ACETYLCYSTEINE ADCO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

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These are all very serious side effects. If you have them, you may have had a serious reaction to ACETYLCYSTEINE ADCO. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects:

Less Frequent Side effects:

- Hypersensitivity
- Headache
- Blurred vision
- Ringing or other noises in one or both of your ears
- Fast heartbeat
- Vomit, diarrhoea, sore or inflammation inside of the mouth, abdominal pain, nausea
- Disturbances of the liver function, a condition in which there is too much acid in the body fluids.
- *Stevens-Johnson syndrome (a rare, serious disorder of the skin and mucous membranes), toxic epidermal necrolysis (painful, life-threatening skin condition), hives, rash, swelling, itching, a skin eruption or rash occurring in certain infectious diseases, itchy skin, flushing.
- joint stiffness
- fever, low blood pressure
- loss of blood from damaged blood vessels
- Tightening of the muscles that line the airways (bronchi) in your lungs, shortness of breath
- Indigestion

Side effects of unknown frequency:

- Sensation of something prevents/stops the air from moving in and out of the airways in your lungs
- swelling of the face

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ACETYLCYSTEINE ADCO.

You can report side effects to the **Adcock Ingram Pharmacovigilance** department by e-mail to Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011 635 0134.

By reporting side effects, you can help provide more information on the safety of ACETYLCYSTEINE ADCO.

5. How to store ACETYLCYSTEINE ADCO:

Store in cool, dry place at or below 25 °C.

Protect from light.

Keep the tubes tightly closed in order to protect from moisture.

Keep the tube in the carton until required for use.

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Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton / tube.

Return all unused medicine to your pharmacist for proper disposal.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What ACETYLCYSTEINE ADCO contains:

The active ingredients are:

ACETYLCYSTEINE 200 ADCO:

Each effervescent tablet contains:	
Acetylcysteine	200 mg

ACETYLCYSTEINE 600 ADCO:

Each effervescent tablet contains:	
Acetylcysteine	600 mg

Contains sodium saccharin 20 mg.

The other ingredients are: citric acid, leucine, maltodextrin [E1400], orange flavour, purified water and sodium hydrogen carbonate [E500].

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What ACETYLCYSTEINE ADCO looks like and contents of the pack:

Effervescent Tablet.

200 mg: White to off white round, flat, effervescent tablets

600 mg: white round flat tablets

Polypropylene tube closed with a polyethylene stoppers equipped with silica gel as drying agent. The tube is inserted into cardboard boxes with the leaflet.

ACETYLCYSTEINE 200 ADCO & ACETYLCYSTEINE 600 ADCO Pack sizes: 10's, 20's.

Holder of the certificate of registration:

Adcock Ingram Limited

1 New Road, Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625.

This leaflet was last revised in:

18 September 2025.

Registration number:

ACETYLCYSTEINE 200 ADCO : 57/10.3/0865.863

ACETYLCYSTEINE 600 ADCO : 57/10.3/0866.864.