

Package leaflet: Information for the patient

<Invented name> 600 mg effervescent tablets

For adults

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> 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.

<Invented name> is used to loosen mucus and to ease coughing up in cases of respiratory diseases with viscous mucus.
It should be used in adults only.

2. What you need to know before you take <Invented name>

Do not take <Invented name>

- if you are allergic to acetylcysteine or any of the other ingredients of this medicine (listed in section 6).
- in children under 2 years
Medicines that dissolve phlegm can block the airways of young children, <Invented name> must not be used in children under 2 years of age.
- Due to the high active substance content, <Invented name> must not be used in children and adolescents. Medicines in a suitable strength are available for this.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Invented name>.

- If you suffer from bronchial asthma, do not take this medicine.
- Very rare skin reactions called Stevens-Johnson syndrome and Lyell syndrome have been seen in people taking acetylcysteine. If you notice any changes to your skin or if you get

ulcers inside your mouth, throat or nose, stop using this medicine and talk to your doctor straightaway.

- Speak with your doctor if you have problems coughing up phlegm, as you may need help to drain the phlegm from your airways. The use of <Invented name> may particularly at the start of treatment, lead to a loosening and therefore increased volume of bronchial secretion. If you are not sufficiently capable of coughing this up, your doctor will take appropriate measures.
- Caution is required if you have a past or present history of a stomach or duodenal ulcer, especially when used concomitantly with other medicinal products known to irritate the mucous membrane of the gastrointestinal tract.
- Caution is required in patients with histamine intolerance. Prolonged treatment should be avoided in these patients because <Invented name> influences histamine metabolism and may lead to symptoms of intolerance (e.g. headache, runny nose, itching).
- If you are on a restricted salt diet (see Acetylcysteine Effervescent Tablets contain sodium)
- If you have hereditary problems with some sugars (see Acetylcysteine Effervescent Tablets contain sorbitol)
- If you have liver or kidney problems
- Effervescent tablets can be a choking hazard if swallowed whole, especially in the elderly. Ensure that tablet is fully dissolved before you take it

Consult your doctor if any of the abovementioned warnings apply to you, or have applied to you in the past.

Children and adolescents

Do not give this medicine to children and adolescents (see above “Do not take <Invented name>”).

Other medicines and <Invented name>

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

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

- Antibiotics. This medicine can prevent antibiotics (medicines which control or prevent infections) from working properly. If you are taking antibiotics, make sure you take this medicine two hours before or after taking your antibiotics.
- Cough medicines, which should not be used at the same time as <Invented name>, as you must be able to cough up the loosened phlegm.
- Medicines to treat angina attacks, (tightness in your chest, neck and arm), <Invented name> may increase the blood pressure-lowering effect of nitroglycerin (a medicine used to treat angina). Your doctor will need to monitor your blood pressure if you use nitroglycerin and <Invented name> at the same time.
- Medicines to treat high blood pressure (hypertension). <Invented name> 600 mg Effervescent Tablets may increase the blood pressure lowering effect of angiotensin-converting enzyme (ACE) inhibitors (medicines used to treat high blood pressure). You should not take <Invented name> if you are also taking ACE inhibitors.
- Activated charcoal, used to treat poisoning
- *Changes in the determination of laboratory parameters*
Acetylcysteine may affect the assay of salicylates.
Acetylcysteine may affect the results of the determination of ketone bodies in urine tests

This medicine can make medicines and supplements containing metals like iron, zinc, copper and manganese less effective. If you are taking a supplement that contains metals, make sure you take it at a different time of the day to <Invented name>.

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.

There is little information about the use of acetylcysteine during pregnancy or breastfeeding and your doctor will only recommend this medicine if the benefits of taking it outweigh the risks.

Driving and using machines

<Invented name> has no influence on the ability to drive and use machines.

<Invented name> contains sodium.

This medicine contains 138.79 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 6.94% of the recommended maximum daily dietary intake of sodium for an adult.

<Invented name> contains 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.

<Invented name> contains sorbitol.

This medicine also contains 0.52 mg sorbitol (E420) in each effervescent tablet.

3. How to take <Invented name>

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

Adults

The recommended dose is 1 effervescent tablet each day.

Method of administration

Dissolve the tablet in half a glass of water. Make sure the tablet dissolves completely and then drink immediately.

Duration of treatment will be determined by your doctor based on your symptoms.

If you take more <Invented name> than you should

Taking too much medicine may cause you to feel or be sick, or give you diarrhoea.

If you have taken too many tablets, contact your doctor or pharmacist straightaway.

If you forget to take <Invented name>

Do not take a double dose to make up for a forgotten dose. Take your tablet as soon as you remember, unless it is almost time for your next dose. If it is almost time for your next dose, then just take the next dose as usual.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking <Invented name> and get medical advice straight away if you experience any of these very rare side effects (may affect up to 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.**

Other side effects include:

Uncommon: may affect up to 1 in 100 people

- Hypersensitivity reactions
- Headache
- A ringing sound in the ears (tinnitus)
- A fast heart rate
- Feeling or being sick
- Diarrhoea and vomiting
- 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: may affect up to 1 in 1,000 people

- Tightness of your airways
- Shortness of breath, bronchospasm
- Indigestion
- Heartburn

Very rare: may affect up to 1 in 10,000 people

Allergic shock and bleeding

Not known: frequency cannot be estimated from the available data

- Swelling of the face

Therefore, you should seek medical advice and stop taking <Invented name> if new serious skin and mucous membrane changes occur. You must not continue to take <Invented name>.

Various studies have confirmed a decrease in platelet aggregation (clumping of certain blood constituents) during administration of acetylcysteine. The clinical significance of this is yet unclear.

Counter measures

Stop taking <Invented name> at the first signs of a hypersensitivity reaction (see above). In this case, please contact a doctor.

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 national reporting system listed in [Appendix V](#).

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

5. How to store <Invented name>

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the strip and the carton after “EXP”. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from moisture.
- This medicine does not require any special temperature storage conditions.
- 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 <Invented name> contains

- The active substance is acetylcysteine.
Each effervescent tablet contains 600 mg acetylcysteine.
- The other ingredients are Citric acid (E330), ascorbic acid (E300), sodium citrate dihydrate (E331), sodium cyclamate (E952), saccharin sodium (E954), mannitol (E421), sodium hydrogen carbonate (E500), sodium carbonate (E500), lactose, lemon flavour (containing natural flavouring preparations, natural flavouring substances, flavouring substances, mannitol (E421), maltodextrin, gluconolactone (E575), sorbitol (E420), silica, colloidal anhydrous (E551)).

What <Invented name> 600 mg effervescent tablets look like and contents of the pack

<Invented name> 600 mg effervescent tablets are round, white tablets with a score line on one side. The tablets come in a strip of paper lined with aluminium. <Invented name> 600 mg effervescent tablets are available in cartons of 20 tablets.

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturer

<[To be completed nationally]>

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

Germany: Acetylcystein Stirling Anglian 600 mg Brausetabletten
Ireland: Acetylcysteine Stirling Anglian 600 mg effervescent tablets
Malta: Aceo 600 mg effervescent tablets
United Kingdom: Acepiro 600 mg effervescent tablets

This leaflet was last revised in {month YYYY}.