

Package leaflet: Information for the user

2 McMillan Close, Saltwell Business Park
Low Fell
GATESHEAD
NE9 5BF

DUNELM
Pharmaceuticals Ltd

Aceteff™ 600mg Effervescent Tablets Acetylcysteine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told 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 Aceteff Tablets are and what they are used for
2. What you need to know before you take Aceteff Tablets
3. How to take Aceteff Tablets
4. Possible side effects
5. How to store Aceteff Tablets
6. Contents of the pack and other information

1. What Aceteff Tablets are and what they are used for

Aceteff™ 600mg Effervescent Tablets (called Aceteff tablets in this leaflet) contain the active ingredient acetylcysteine which belongs to a group of medicines called 'mucolytics'. Aceteff tablets are used for problems with the breathing passages (also known as your respiratory tract). Sometimes too much mucus (phlegm) is made or the phlegm is too sticky. The tablets work by making mucus thinner and less sticky so it is easier to cough up.

2. What you need to know before you take Aceteff Tablets

Do not take Aceteff Tablets:

- if you are allergic (hypersensitive) to acetylcysteine or any of the ingredients of this medicine (listed in section 6).
 - if you are under 14 years of age.
- If you are not sure, talk to your doctor, pharmacist or nurse before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aceteff tablets and tell them if you have:

- liver or kidney problems
- asthma
- a history of stomach ulcers
- intolerance to histamine. If you are not able to tolerate food and drinks that contain large amount of histamine such as wine, tomatoes or processed food, then Aceteff tablets are not suitable for you because Aceteff affects how histamine is broken down in the body. The most common symptoms of histamine intolerance are migraine headaches, flushing, hives and rhinitis (stuffy, runny nose) and itching.

Serious skin rashes (Stevens-Johnson syndrome and Lyell syndrome) have rarely been reported with the use of acetylcysteine. The rash can often involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are frequently followed by flu-like symptoms of fever, headache and body ache. The rash may progress to widespread blistering and peeling of the skin. If you develop a rash or these skin symptoms you should stop taking these tablets and contact your doctor immediately.

Take care to dissolve the tablet fully in water before taking the medicine. This is because the effervescent ("fizzy") formulation poses a risk of choking if the tablet is swallowed whole.

Other medicines and Aceteff Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those you may have bought yourself without prescription.

Aceteff and cough medicines:

If Aceteff tablets are used in combination with cough relieving medicines that help to stop you coughing, you may experience a dangerous build-up of secretions. For this reason you must consult your doctor or pharmacist before taking cough medicine with Aceteff tablets.

Aceteff and antibiotics:

Some antibiotics such as aminoglycosides, penicillin and tetracycline are not as effective when taken at the same time as your Aceteff tablets. If you need to take antibiotics and Aceteff tablets you should leave at least two hours between taking these medicines. This does not apply to antibiotics such as cefixime and loracarbef, these medicines can be taken at the same time as acetylcysteine.

Aceteff and activated charcoal

Using activated charcoal can reduce the effects of Aceteff.

Aceteff and glyceryl trinitrate

Simultaneous administration of Aceteff tablets and glyceryl trinitrate may increase the normal effect of glyceryl trinitrate which is used to help widen the blood vessels in patients with chest pain (angina).

If your doctor considers combined treatment with these medicines to be necessary, you will be monitored for possible lowering of blood pressure (hypotension), which can be serious and may be indicated by headaches.

Changes in certain laboratory tests

Acetylcysteine may affect a test for salicylate (such as aspirin) in the blood. It may also affect the results when testing for ketones in urine. Ketones are produced by the breakdown of fat in the body, for example in people with high levels of sugar in the blood.

Taking Aceteff Tablets with food and drink

Your Aceteff tablets should be taken after you have eaten. See section 3: How to take Aceteff tablets, for more details.

Pregnancy and lactation

Always consult your doctor or pharmacist before taking/using any medicines. There is insufficient experience of the use of Aceteff Tablets in pregnant or breast-feeding women. You should only take Aceteff Tablets during pregnancy or whilst breast-feeding if your doctor considers this absolutely necessary.

If you are pregnant or breast-feeding, or 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

Taking Aceteff Tablets should not affect your ability to drive or use machinery.

Important information about some of the ingredients in your tablets

Aceteff tablets contain aspartame (an artificial sweetener sometimes called NutraSweet). Aspartame is a source of phenylalanine, an amino acid which is a building block of protein. Phenylalanine may be harmful to people with the genetic disorder called phenylketonuria.

One Aceteff tablet contains 6.3mmol (145mg) sodium. To be taken into consideration by patients on a controlled salt diet. Sodium is part of salt (sodium chloride).

3. How to take Aceteff Tablets

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

The recommended dose is given in the table below:

Age	Single dose	Total daily dose
Adolescents over 14 and adults	One tablet once a day	One tablet (equivalent to 600mg acetylcysteine)

How long you use your tablets will depend upon the nature and severity of your illness and this will be decided by your doctor.

For the treatment of chronic bronchitis or cystic fibrosis your treatment will normally be given over a long period of time to help prevent infection.

Dissolve your tablet completely in a glass of water before use and drink the entire contents of the glass. This medicine should be taken after food.

If symptoms worsen or if there is no improvement after 5 days, you should consult a doctor.

A slight odour of hydrogen sulphide (rotten eggs) may occur over time and is part of the normal aging process of the tablets. This is harmless and does not affect the usefulness of the tablets.

Children under 14 years of age

Aceteff™ 600mg Effervescent Tablets are not suitable for children under 14 years of age.

If you take more Aceteff tablets than you should you may experience stomach ache, nausea, vomiting, diarrhoea. Severe side effects and symptoms of intoxication have not been seen even in the event of massive overdose. If you take too many tablets you should contact your doctor immediately or go to your nearest casualty department. Remember to take the pack and any remaining tablets with you.

If you forget to take your Aceteff tablets simply take your next dose on time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Aceteff tablets do so following the advice of your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Please do not stop taking Aceteff tablets without consulting your doctor.

4. Possible side effects

Like all medicines, Aceteff tablets can cause side effects, although not everybody gets them.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Serious side effects

Potentially life-threatening skin rashes (Stevens-Johnson syndrome and Lyell syndrome) have been reported, see section 2.

The following side effects have been reported;

Uncommon side effects (probably affecting fewer than 1 in 100 people)

- hypersensitivity
- headache
- ringing in the ears
- fever
- swelling of the skin
- increase in heart rate
- lowering of blood pressure
- stomach ache
- feeling or being sick
- diarrhoea
- inflammation of the mouth

Rare side effects (probably affecting fewer than 1 in 1,000 people)

- shortness of breath
- sudden difficulty breathing
- indigestion

Very rare (probably affecting fewer than 1 in 10,000 people)

- allergic reactions
- bruising (affecting the whole body)
- skin rashes (Stevens-Johnson syndrome and Lyell syndrome)

A reduction in blood platelets which increases the risk of bleeding or bruising has also been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aceteff Tablets

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 carton and on the tube. The expiry date refers to the last day of that month.

Do not store above 25°C. Re-seal the tube immediately after removing a tablet. Store your medicine in the original packaging to protect the tablets from light and moisture.

Do not use this medicine if you notice that the tablets look moist or are crumbly.

Do not throw away medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Aceteff Tablets contain:

The active substance is acetylcysteine and each tablet contains 600mg of active substance.

The other ingredients are sodium hydrogen carbonate, anhydrous citric acid, aspartame (E951) and lemon flavouring.

What Aceteff Tablets look like and contents of the pack:

Aceteff Tablets are white, flat, circular tablets approximately 18mm in diameter and have the characteristic smell of lemon and of acetylcysteine (like hydrogen sulphide or rotten eggs). They are provided in white polypropylene tubes containing 10, 20 or 15 tablets, closed with tamper evident plastic caps with integrated desiccant. The pack of 30 tablets contains two tubes of 15 tablets in an outer carton. Not all pack sizes may be available.

Marketing authorisation holder:

Dunelm Pharmaceuticals Limited
2 McMillan Close
Saltwell Business Park
Low Fell
GATESHEAD
NE9 5BF

Manufacturer:

Temmler Pharma GmbH
Temmlerstraße 2
35039 Marburg
Germany

PL36892/0002

This leaflet was last revised in March 2020.

300001-C-009 51744162