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PACKAGE LEAFLET: INFORMATION FOR THE USER

Acetylcysteine 600mg Effervescent Tablets

(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, 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 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

- What Acetylcysteine Effervescent Tablets are and what they are used for
- What you need to know before you take Acetylcysteine Effervescent Tablets
- How to take Acetylcysteine Effervescent Tablets
- Possible side effects
- How to store Acetylcysteine Effervescent Tablets
- Contents of the pack and other information

1. WHAT ACETYL-CYSTEINE EFFERVESCENT TABLETS ARE AND WHAT THEY ARE USED FOR

Acetylcysteine Effervescent Tablets contain a medicine called acetylcysteine. This belongs to a group of medicines called mucolytics. It works by making the mucus (phlegm) less sticky which makes the mucus easier to cough up. Acetylcysteine is used for problems with the breathing passages (respiratory tract).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACETYL-CYSTEINE EFFERVESCENT TABLETS

Do NOT take Acetylcysteine Effervescent Tablets if you:

- Are allergic to acetylcysteine or any of the other ingredients of this medicine (listed in section 6)
- Are under 14 years of age.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Acetylcysteine Effervescent Tablets:

- If you have asthma
- If you have a history of stomach ulcers
- If you are allergic 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 Acetylcysteine Effervescent Tablets are not suitable for you because acetylcysteine 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.
- 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.

Serious skin rashes (Stevens-Johnson syndrome and Lyell's 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**.

Effervescent tablets can be a choking hazard if swallowed whole, especially in the elderly. Ensure that the tablet is fully dissolved before you take it.

Other medicines and Acetylcysteine Effervescent Tablets

Please tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. In particular:

- Cough-relieving medicines (antitussives) used in combination with acetylcysteine can cause a dangerous build-up of secretions
- Activated charcoal can reduce the effects of acetylcysteine
- Antibiotics (e.g. aminoglycosides, penicillins, tetracycline) may not work as well when taken at the same time as acetylcysteine. If you need to take antibiotics and acetylcysteine 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
- Glyceryl trinitrate used to treat chest pain (angina). Simultaneous administration of acetylcysteine 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. 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.

Effects of Acetylcysteine Effervescent Tablets on 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.

Acetylcysteine Effervescent Tablets with food, drink and alcohol

Acetylcysteine Effervescent Tablets should be taken after food.

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.

Acetylcysteine Effervescent Tablets should not be taken during pregnancy or breast-feeding.

If you are unsure you should talk to your doctor before taking these tablets.

Driving and using machines

Acetylcysteine Effervescent Tablets should not affect your ability to drive or use machinery.

Acetylcysteine Effervescent Tablets contain sodium

This medicine contains 356.8 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 17.84% of the recommended maximum daily dietary intake of sodium for an adult.

Acetylcysteine Effervescent Tablets contain sorbitol

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person

cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. HOW TO TAKE ACETYL-CYSTEINE EFFERVESCENT TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. For oral administration only. Acetylcysteine Effervescent Tablets should be dissolved completely in a glass of water before use and taken after food.

Adults and children aged 14 years and over:

The usual dose is 1 tablet, once daily. Dissolve the tablet in a glass of water and take after food.

This medicine can be taken for up to 5 days for acute respiratory problems. Longer-term treatment may be needed for chronic respiratory disorders.

Children under the age of 14 years

Acetylcysteine Effervescent Tablets are not suitable for children under the age of 14.

If you take more Acetylcysteine Effervescent Tablets than you should

If you take more Acetylcysteine Effervescent Tablets than you should, talk to your doctor or contact your nearest hospital casualty department immediately. Take your tablet pack with you. You may have diarrhoea, heartburn, stomach ache or feel sick.

If you forget to take Acetylcysteine Effervescent Tablets

If you have forgotten to take a dose, leave out that dose completely. Take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose. If you have trouble remembering to take your tablets, tell your doctor or pharmacist.

If you stop taking Acetylcysteine Effervescent Tablets

You should talk to your doctor or pharmacist before stopping taking these tablets.

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 everyone gets them.

Stop taking Acetylcysteine Effervescent Tablets and see a doctor or contact your nearest hospital casualty department immediately:

- If you have swelling of the lips, throat or tongue, difficulty in swallowing or breathing. This could be a sign of an allergic reaction
- Any changes to the skin or mucus membranes (such as your nose, mouth, lips and genitals) including skin rashes, blistering or peeling of the skin. These may be accompanied by flu-like symptoms. These could be signs of serious skin reactions such as Stevens-Johnson Syndrome or Lyell's Syndrome.

Other side effects reported with this medicine are shown below:

Uncommon (may affect up to 1 in 100 people)

- Headache
- ringing in the ears (tinnitus)
- Increased heart rate
- Feeling sick or being sick
- Diarrhoea
- Stomach pains
- Swelling in the mouth and swelling of the lips
- Skin rashes and itching
- Fever
- Low blood pressure.

Rare (may affect up to 1 in 1,000 people)

- Indigestion
- Shortness of breath.

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

- Bleeding in the upper respiratory tract.

Not known (frequency cannot be estimated from the available data)

- Swelling of the face.

Laboratory tests

Your doctor may want to perform some laboratory tests while you are taking these tablets.

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 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 ACETYL-CYSTEINE EFFERVESCENT TABLETS

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

Do not store above 25°C.

For sachet packaging:

Store in the original package to protect from moisture and light.

For polypropylene tube packaging:

Keep the tube tightly closed. Store in the original package to protect from moisture and light.

Do not use this medicine after the expiry date which is stated on the blister and carton or label. The expiry date refers to the last day of that month. Do not use this medicine if you notice discolouration of the tablets.

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 Effervescent Tablets contain:

The active substance is acetylcysteine. Each tablet contains 600 mg acetylcysteine.

The other ingredients are: Ascorbic acid (Vitamin C), Citric acid, Sodium hydrogen carbonate (see section 2), Sodium carbonate (see section 2), Sorbitol (E420) (see section 2), Macrogol 6000, Sodium citrate (see section 2), Sodium saccharin (see section 2), Flavour (Lemon).

What Acetylcysteine Effervescent Tablets look like and contents of the pack

Acetylcysteine Effervescent Tablets are white flat-faced tablets with bevelled edges 25mm in diameter.

Acetylcysteine Effervescent Tablets are available in the following presentations:

A carton containing 2 tubes of 10 tablets with tamper evident plastic caps with inbuilt desiccant. Tubes containing 12 tablets with tamper evident plastic caps with inbuilt desiccant.

A carton containing 10 tablets packed into individual sachets.

A carton containing 20 tablets packed into individual sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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