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PACKAGE LEAFLET: INFORMATION FOR THE USER

Acetylcysteine 600mg Capsules

(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:

1. **What Acetylcysteine Capsules are and what they are used for**
2. **What you need to know before you take Acetylcysteine Capsules**
3. **How to take Acetylcysteine Capsules**
4. **Possible side effects**
5. **How to store Acetylcysteine Capsules**
6. **Contents of the pack and other information**

1. WHAT ACETYLCYSTEINE CAPSULES ARE AND WHAT THEY ARE USED FOR

Acetylcysteine Capsules 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 ACETYLCYSTEINE CAPSULES

Do NOT take Acetylcysteine Capsules 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 Capsules:
- If you have asthma, in the event of narrowing of the airways (bronchospasms), use must be stopped immediately and appropriate treatment started.
- If you have difficulty coughing up mucus in your airways, the airways must be cleared with physiotherapy (postural drainage) or, if necessary, kept clear by suction (aspiration).
- If you suffer from, or have suffered from, stomach ulcers, or are at risk of gastrointestinal bleeding, particularly when you are simultaneously using other medicines known to irritate the gastric mucosa
- If you are allergic to histamine. If you are not able to tolerate food and drinks that contain large amounts of histamine such as wine, tomatoes or processed food, then Acetylcysteine Capsules 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 have liver or kidney problems.
- If you experience vomiting (acetylcysteine may increase the intensity of vomiting)
- If you experience allergic symptoms, including hives (urticaria) (discontinue use if the symptoms cannot be medically controlled).

Serious skin rashes (Steven-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 capsules and contact your doctor immediately.**

Other medicines and Acetylcysteine Capsules
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. It is best to avoid simultaneous use of cough suppressants with mucolytic medications, such as acetylcysteine, as this reduces the cough reflex and could lead to a buildup of mucus.
- 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 (nitroglycerin) used to treat chest pain (angina). Simultaneous administration of acetylcysteine and glyceryl trinitrate (nitroglycerin) may increase the normal effect of glyceryl trinitrate (nitroglycerin) 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.
- Acetylcysteine and heavy metal salts, such as gold, iron, or calcium salts, can influence each other's action. It is therefore better to leave a time interval between the intake of Acetylcysteine and these salts, or to choose a different route of administration.
- Simultaneous use of acetylcysteine and carbamazepine could lead to reduced efficacy of carbamazepine.

Effects of Acetylcysteine Capsules 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 Capsules with food, drink and alcohol
Acetylcysteine Capsules 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 Capsules should not be taken during pregnancy or breast-feeding.
If you are unsure you should talk to your doctor before taking these capsules.

Driving and using machines
Acetylcysteine Capsules should not affect your ability to drive or use machinery.

3. HOW TO TAKE ACETYLCYSTEINE CAPSULES

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. Swallow the capsule with a drink of water. Acetylcysteine Capsules should be taken after food.

Adults and children aged 14 years and over:
The usual dose is 1 capsule, once daily. Your doctor will decide how long you should take this medicine for.

Children under the age of 14 years:
Acetylcysteine Capsules are not suitable for children under the age of 14.

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

If you forget to take Acetylcysteine Capsules
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 capsules, tell your doctor or pharmacist.

If you stop taking Acetylcysteine Capsules
You should talk to you doctor or pharmacist before stopping taking these capsules.

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 Capsules 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 and loss of consciousness. 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, itching, blistering or peeling of the skin. These may be accompanied by flu-like symptoms. These could be signs of serious skin reaction 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.
- Dizziness

Not known (frequency cannot be estimated from the available data)
- Swelling of the face.

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 ACETYLCYSTEINE CAPSULES

Keep this medicine out of the sight and reach of children.
Store below 25˚C.
Do not use this medicine after the expiry date which is stated on the blister and carton. 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 Capsules contain:
The active substance is acetylcysteine. Each capsule contains 600 mg acetylcysteine.
The other ingredients are: Crospovidone C1-SF, Stearic acid, Gelatine and Titanium dioxide.

What Acetylcysteine Capsules look like and contents of the pack
Acetylcysteine Capsules are white hard capsules with an almost white crystalline powder filling.
Acetylcysteine Capsules are available in a carton containing 30 capsules packed in PVC/PVDC blister packs.

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