ACETYLCYSTEINE SANDOZ EFFERVESCENT TABLET

Consumer Medication Information Leaflet (RiMUP)

Acetylcysteine (200 mg and 600 mg)

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WHAT IS ACETYLCYSTEINE SANDOZ USED FOR

Acetylcysteine Sandoz is used to reduce the thickness and secretions from the respiratory tract.

HOW ACETYLCYSTEINE SANDOZ WORKS

Acetylcysteine Sandoz contains Acetylcysteine. Acetylcysteine helps to reduce thickness of the mucus in the respiratory tract, and has been shown to dramatically effect in sputum.

BEFORE YOU USE ACETYLCYSTEINE SANDOZ

- *When you must not use it*

- If you are allergic (hypersensitive) to Acetylcysteine, or to any of the ingredients.
- If you have inherited disorder that causes an amino acid called phenylalanine to build up in your body or you are allergic to aspartame (artificial sweetener).
- In children under 2 years.
- If you have severe asthma attacks.
- If you have chronic duodenal or gastric ulcer disease.

- *Before you start use it*

- Patients with asthma should be carefully monitored. Treatment with acetylcysteine should be stopped when breathing difficulties occur. The sulfur odour on opening the sachets does not indicate deterioration of the product, but is due to the active ingredient.
- Other medicines should not be used with acetylcysteine solution.
- Caution is advised if you have histamine intolerance.
- Caution is advised if you need to be on a controlled sodium (low sodium/ low salt) diet.
- Caution is advised to patients who have lactose or fructose intolerance.
- Tell your doctor if you are pregnant, or plan to become pregnant or breastfeeding. Your doctor will discuss with you the risks and benefits involved.

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including medicines obtained without a prescription.
Oral antibiotics should be administered separately and at an interval of at least 2 hours.
Activated charcoal may reduce the effect of acetylcysteine.

HOW TO USE ACETYLCYSTEINE SANDOZ

- *How much to use*

Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

200 mg:

Children over 2 years: 100 – 200 mg 2 times a day
Adult: 200 mg 3 times a day

600 mg:

Adult: 600 mg once daily

Dissolve an effervescent tablet in about half a glass of water, avoid the addition of other medicines to the solution. Take it after meals. Use as directed by your physician.

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

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking for as long as your doctor recommends.

- *If you forget to use it*

If you miss a dose, leave it out and take the next dose when it is due. After that, just carry on as before. Do not double the dose.
If you have any further questions about these medicines, ask your doctor or pharmacist.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the nearest emergency department if you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Bring the pack with any remaining tablets with you.

WHILE YOU ARE USING IT

- *Things you must do*

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Acetylcysteine Sandoz.
- Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Acetylcysteine Sandoz to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines
The medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy, tired, or give you a headache, do not drive or use machines. Contact your doctor immediately.

SIDE EFFECTS

Like all medicines, Acetylcysteine Sandoz can cause side effects, although not everybody gets them. Visit your doctor or pharmacist

immediately if you experience any side effects after taking this medicine.

Acetylcysteine Sandoz may cause severe allergy and serious skin reactions. Stop using Acetylcysteine Sandoz and seek medical assistance immediately if you experience any of the following symptoms:

- Severe allergy: breathing difficulties, light headedness, skin swellings or rash.
- Severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)].

STORAGE AND DISPOSAL OF ACETYLCYSTEINE SANDOZ

- *Storage*

Do not store above 30°C.
Keep out of the reach and sight of children.
Do not use your medicine after the expiry date.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

PRODUCT DESCRIPTION

- *What it looks like*

Acetylcysteine Sandoz 200 mg effervescent tablet

White, round tablet, faultless surface, scored on one side, smell of blackberries, with a diameter of 18 mm.

The effervescent tablet can be divided into equal doses.

Acetylcysteine Sandoz 600 mg effervescent tablet

White, round tablet, faultless surface, scored on one side, smell of blackberries, with a diameter of 20 mm.

The effervescent tablet can be divided into equal doses.

- *Ingredients*

Active ingredient

Each **Acetylcysteine Sandoz 200 mg** effervescent tablet contains 200 mg acetylcysteine.

Each **Acetylcysteine Sandoz 600 mg** effervescent tablet contains 600 mg acetylcysteine.

Inactive ingredients

Ascorbic acid, sodium citrate dihydrate, mannitol, saccharin sodium, citric acid anhydrous, sodium cyclamate, sodium hydrogen carbonate, lactose anhydrous, sodium carbonate anhydrous, blackberry flavour.

- *MAL numbers*

Acetylcysteine Sandoz 200 mg effervescent tablet:
MAL17107049XCZ
Acetylcysteine Sandoz 600 mg effervescent tablet:
MAL17107050XCZ

MANUFACTURER

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PRODUCT REGISTRATION HOLDER

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