

ALPAC Effervescent Tablet 600mg

N-Acetylcysteine (600mg)

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What ALPAC is used for

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

How ALPAC works

ALPAC contains the active ingredient known as N-Acetylcysteine, belonging to a group of medicines called mucolytic which works by thinning the mucus (phlegm) in the respiratory tract so that it can be coughed up more easily.

Before you use ALPAC

When you must not use it

You must not use ALPAC if:

- You are allergic to N-Acetylcysteine or any of the other ingredients in this medicine
- You are a child under 2 years of age

Before you start use it

Talk to your doctor or pharmacist before taking ALPAC if:

- If you suffer from asthma. You may need to be monitored closely while taking this medication. Treatment with N-acetylcysteine should be stopped when breathing difficulties occur
- If you are an elderly or debilitated patient with severe respiratory insufficiency
- If you have or had history of peptic ulceration as ALPAC may irritate your gastric wall. In particular if you use other drugs known to irritate the gastric wall.
- If you need to be on a controlled sodium (low sodium/ low salt) diet
- If you have histamine intolerance as N-Acetylcysteine may cause symptoms of intolerance

(headache, vasomotor rhinitis, itching)

- If you are due to have any blood or urine tests, as N-Acetylcysteine can interfere with some laboratory test
- You are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription

- Cough suppressants
- Activated charcoal, used to treat poisoning and traveler's diarrhea
- Antibiotics used to treat bacterial infections. N-Acetylcysteine can prevent some antibiotics from working properly if they are taken at the same time as it. If this applies to you, you should take this medicine either two hours before or after taking your antibiotics.
- Nitroglycerin used to treat angina attacks since N-Acetylcysteine may increase the blood-pressure lowering effect nitroglycerin
- Carbamazepine since N-Acetylcysteine may decrease its effect

Pregnancy and lactation

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 a limited amount of data from the use of N-Acetylcysteine in pregnant women.

It is not known whether N-Acetylcysteine is excreted in breast milk. Only use N-Acetylcysteine after careful consideration of the benefits and risks during breast-feeding.

How to use ALPAC

How much to use

Adult: 1 effervescent tablet (600mg) once daily.

Dissolve the effervescent tablet in a glass of water, mix it and drink the solution immediately. It is preferable not to mix other medication with ALPAC Effervescent Tablet 600mg .

When to use it

Take your medicine at the same time every day.

Patients who have difficulty coughing up phlegm (elderly and weakened patients) are advised to take the effervescent tablet in the mornings

How long to use it

Use as prescribed. Check with your doctor or pharmacist if you are not sure.

If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think 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.

Taking too many tablets may cause nausea, vomiting and diarrhea.

While you are using it

Things you must do

After taking N-Acetylcysteine, you may notice an increase in phlegm volume. Expel the phlegm by coughing it out to keep the airways clear. If you have difficulty breathing after taking this medicine (especially if you are asthmatic), discontinue taking and seek medical attention promptly.

Take your medicine exactly as your doctor has told you.

Things you must not do

Do not mix other medications you are consuming with ALPAC solution.

Do not store a solution of ALPAC for later use. Once dissolved in water, consume it immediately.

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Do not stop taking your medicines without consulting your doctor.

Do not give this medication to anyone else even if they have the same condition as you.

Things to be careful of

On opening the sachet, ALPAC may smell of sulphur (rotten eggs). This is a normal characteristic of this medicine and does not mean that it is not safe to use.

Driving and using machines

ALPAC should not affect your ability to drive or operate machinery. If you experience side effects which may affect these abilities, do not drive or operate machinery until the effects have completely disappeared.

Hypersensitivity reactions

There have been very rare reports of serious hypersensitivity reactions with (high) fever, skin redness, joint pains and/or eye infection (Stevens-Johnson syndrome), and acute hypersensitivity reactions accompanied by fever and blisters on the skin or peeling of the skin (Lyell syndrome) which were associated with the use of ALPAC. However, in most cases, at least one other medicine was used, which was most likely the cause for this reaction.

Side effects

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

ALPAC may cause severe allergy and serious skin reactions. Stop using ALPAC 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

If any of the following side effects occur, immediately stop using ALPAC and contact your doctor or go the emergency room of a nearby hospital. (occurs in fewer than 1 in 10,000 users).

- Shock (severe drop in blood pressure, paleness, restlessness, weak pulse, clammy skin,

decreased consciousness) due to a sudden widening of the blood vessels as a result of severe hypersensitivity to certain ingredients (anaphylactic shock).

- Sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and skin rash, often as a result of an allergic reaction (angioedema).

The above mentioned reactions are very serious side effects. If you experience any of these reactions it is possible that you have a hypersensitivity reaction to ALPAC Effervescent Tablet.

Inform your doctor if you experience any of the following side effects:

- Shortness of breath due to muscle cramping of the airways (bronchospasms).
- Difficulty breathing, shortness of breath or breathlessness (dyspnoea).
- Impaired digestion with symptoms of fullness in the upper abdomen, gastric pain, belching, nausea and heartburn (dyspepsia).
- Headache
- Ringing in the ears (tinnitus)
- Inflammation of the oral mucous lining (stomatitis)
- Diarrhea
- Fever (pyrexia)
- Low blood pressure
- Abdominal pain
- Nausea
- Vomiting

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ALPAC

Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not store any medicine in the bathroom, or near a sink, or on a windowsill. Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

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

ALPAC Effervescent Tablets 600mg are round, flat, white to yellowish effervescent tablets. It is clear with air bubbles after dissolve in water. The tablets are packaged in a propylene tube with a polyethylene cap and a desiccant. A tablet container contains 10 effervescent tablets.

Ingredients

Active ingredient(s)

- N-Acetylcysteine 600mg

Inactive ingredients

- Sodium Bicarbonate
- Citric acid
- Sucralose
- Orange flavour

MAL number(s):

ALPAC Effervescent Tablet 600mg
MAL *****

Manufacturer

Alpex Pharma SA
Via Cantonale
6805 Mezzovico-Vira
Switzerland

Product Registration Holder

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