

ALPAC Effervescent Tablet 600mg - Patient Information Leaflet

What is ALPAC Effervescent Tablet 600mg?

ALPAC Effervescent Tablet 600mg contains the active ingredient N-Acetylcysteine that belongs to group of medicines called mucolytics.

What is ALPAC Effervescent Tablet 600mg used for?

ALPAC Effervescent Tablet 600mg breaks down and loosens thick mucus, making it runny and easy to cough up. N-Acetylcysteine is used in the treatment of respiratory conditions associated with excessive mucus production such as bronchitis (inflammation of the mucous membrane in the airways), emphysema, mucoviscidosis (cystic fibrosis) and bronchiectasis (chronic widening of an airway passage).

What you need to know before taking ALPAC Effervescent Tablet 600mg?

Do not use ALPAC Effervescent Tablets 600mg

- If you are allergic to N-Acetylcysteine or any of the other ingredients of this medicine.
- Children under 2 years of age may not use this medicine

How do I use ALPAC Effervescent Tablet 600mg?

Adults:

1 effervescent tablet once daily.

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

Always use this medicine exactly as prescribed. Check with your doctor or pharmacist if you are not sure. The duration of treatment should be 5 to 10 days in the acute treatment, whereas it may be continued in the chronic states for several months, according to the advice of the doctor. Do not use this medicine for longer than 10 days without consulting a doctor.

Warnings and precautions

- If you suffer of bronchial asthma then you should not take this medicine.
- If you have or have had a peptic ulcer, as ALPAC Effervescent Tablet 600mg may irritate your gastric wall. In particular if you use other drugs known to irritate the gastric wall.
- 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 Effervescent Tablet 600mg. However, in most cases, at least one other medicine was used, which was most likely the cause for this reaction.
- If new changes to the skin or mucous membranes occur, you must immediately consult a doctor and stop using N-Acetylcysteine.

As the thick phlegm becomes more fluid, its volume will increase, especially at the beginning of the treatment. If you are unable to efficiently cough up this fluid phlegm, you must consult a doctor so that adequate measures can be taken to remove the phlegm.

- Medicines, such as ALPAC Effervescent Tablet 600mg that dissolve phlegm (mucolytics) may block the airways of children under the age of 2, due to the characteristics of the airways in this age group. This may limit their ability to cough up phlegm. Therefore, ALPAC Effervescent Tablet 600mg must not be used by children under the age of 2.
- When opening the package you may perceive a mild sulfur odour (smell of rotten eggs). This is a property of the active ingredient and is normal. It does not indicate that the medicine has changed.

Consult your doctor if any of the abovementioned warnings are applicable to you, or have applied to you in the past.

As ALPAC Effervescent Tablet 600mg contains sodium (115 mg per tablet) this has to be taken into consideration by patients on a controlled sodium diet.

Other medicines and ALPAC Effervescent Tablet 600mg

If you are using other medicines, do not dissolve them together with ALPAC Effervescent Tablet 600mg

If you need to use medicines to control or prevent infections (antibiotics), you are advised to take these two hours before or after ALPAC Effervescent Tablet 600mg.

Cough suppressants should not be used at the same time as ALPAC Effervescent Tablet 600mg, as you must be able to cough up the loosened phlegm.

ALPAC Effervescent Tablet 600mg may increase the blood pressure-lowering effect of nitroglycerin[a medicine used against tight painful feeling in the chest (angina pectoris)]. Caution is advised.

If you use activated charcoal (a medicine against traveller's diarrhoea), it may decrease the effect of ALPAC Effervescent Tablet 600mg.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines apart from ALPAC Effervescent Tablet 600mg, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Pregnancy

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

Breast-feeding

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. If you are pregnant or breast-feeding, contact your doctor or pharmacist before any medicine.

Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If any of the following side effects occur, immediately stop using ALPAC Effervescent Tablet 600mg and contact your doctor or go the emergency room of a nearby hospital.

- 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 600mg. This very serious side effect is very rare (occurs in fewer than 1 in 10,000 users).

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). These side effects are rare (occurring in 1 to 10 in every 10,000 users).
- Hypersensitivity. This may manifest itself as bronchospasms and dyspnoea (see above), rapid heart rate (tachycardia), itching (pruritus), skin rash with severe itching and small bumps (urticaria) and angioedema.
- Headache
- Ringing in the ears (tinnitus)
- Rapid heart rate (tachycardia)
- Inflammation of the oral mucous lining (stomatitis)
- Diarrhoea
- Fever (pyrexia)
- Low blood pressure
- Abdominal pain
- Nausea
- Vomiting

These side effects are uncommon (occurring in 1 to 10 in every 1,000 users).

If you suffer from gastric or duodenal ulcers or have had these in the past, N-Acetylcysteine may have an unfavourable effect on your gastrointestinal mucous membrane.

If any of the side effects become serious, or you notice any side effects not mentioned in this leaflet, contact your doctor or pharmacist.

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.

If you use more ALPAC Effervescent Tablet 600mg than you should

Symptoms that may occur are: nausea, vomiting and diarrhoea. If you have used too many ALPAC Effervescent Tablet 600mg, immediately contact your doctor or pharmacist.

If you forget to take ALPAC Effervescent Tablet 600mg

If you have forgotten to take a dose and it is almost time for the next dose, do not take the 'forgotten' dose. Do not take a double dose to make up for a forgotten dose.

Driving and using machines

There are no data available on the effect of N-Acetylcysteine on the ability to drive. An effect is, however, not likely.

How to store ALPAC Effervescent Tablet 600mg

Store below 30°C. Protect against heat and moisture.

Shelf life

2 Years

Do not use this medicine after the expiry date, which is stated on the package after. The expiry date refers to the last day of that month.

What ALPAC Effervescent Tablet 600mg contains?

The active substance of ALPAC Effervescent is N-Acetylcysteine 600mg. The other excipients are Sodium hydrogen carbonate (E500), Citric acid (E330), Sucralose (E955), Orange flavour (contains Orange Essential Oil, Orange Essential Oil Terpenless, Gum Arabic (E414), butylhydroxyanisole (E320), Citric acid monohydrate (E330) and Maltodextrin (DE19)

What ALPAC Effervescent Tablets 600mg looks like and contents of the pack

ALPAC Effervescent Tablets 600mg are round, flat, white to yellowish effervescent tablets. The tablets are packaged in a propylene tube with a polyethylene cap and a desiccant. A tablet container contains 10 effervescent tablets. You may sometimes smell a mild sulfur odour when opening the package. This is normal and harmless.

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