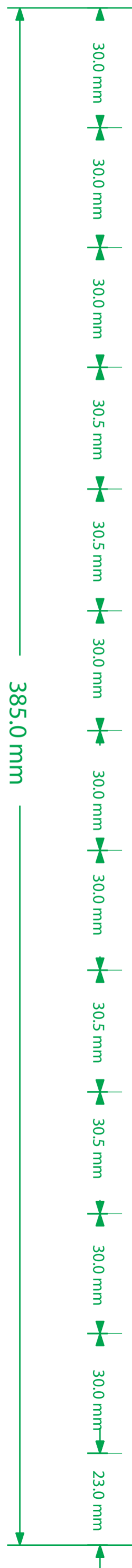


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|----------------|-----------------------------------|
| Product Name | NACSYS 600mg Effervescent Tablets |
| MA Number | PL 44490/0006 |
| Component | Package Leaflet |
| Artwork Number | PL-ACE-EFFTAB-600-Rev 01 |

FRONT



Package leaflet: Information for the user
NACSYS 600 mg 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What NACSYS 600 mg effervescent tablets are and what they are used for
2. What you need to know before you take NACSYS 600 mg effervescent tablets
3. How to take NACSYS 600 mg effervescent tablets
4. Possible side effects
5. How to store NACSYS 600 mg effervescent tablets
6. Other information

1. WHAT NACSYS 600 MG EFFERVESCENT TABLETS ARE AND WHAT THEY ARE USED FOR

Acetylcysteine breaks down and loosens thick phlegm, making it runny and easy to cough up. Acetylcysteine is used in the treatment of airway diseases such as bronchitis (inflammation of the mucous membranes in the airways), emphysema, mucoviscidosis (cystic fibrosis) and bronchiectasis (chronic widening of an airway passage).

NACSYS 600 mg Effervescent tablets are only indicated for adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NACSYS 600 MG EFFERVESCENT TABLETS

Do not take NACSYS 600 mg effervescent tablets

- If you are allergic to acetylcysteine or any of the other ingredients of this medicine (listed in section 6).
- Children under 2 years of age must not take this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking NACSYS 600 mg effervescent tablets:

- Acetylcysteine can cause shortness of breath due to muscle cramping of the airways (bronchospasms) especially in patients with asthma. If this occurs, immediately stop the treatment and consult a doctor.
- If you have or have had a peptic ulcer, as NACSYS 600 mg effervescent tablets 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 NACSYS 600 mg effervescent tablets. 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 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 NACSYS 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, NACSYS must not be used by children under the age of 2.
- NACSYS 600 mg effervescent tablets are not suitable for use in children and adolescents younger than 18.
- 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 above mentioned warnings apply to you or have applied to you in the past.

Other medicines and NACSYS 600 mg effervescent tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are using other medicines, do not dissolve them together with NACSYS 600 mg effervescent tablets.

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

Cough suppressants should not be used at the same time as NACSYS 600 mg effervescent tablets, as you must be able to cough up the loosened phlegm.

NACSYS 600 mg effervescent tablets 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 for traveller's diarrhoea), it may decrease the effect of NACSYS 600 mg effervescent tablets.

Pregnancy and breast-feeding

Pregnancy

There is a limited amount of data from the use of acetylcysteine in pregnant women.

Animal studies do not indicate direct or indirect harmful effects on pregnancy, or the development of the child, before, during or after birth. Only use NACSYS 600 mg effervescent tablets after careful consideration of the benefits and risks during pregnancy.

Breast-feeding

It is not known whether acetylcysteine is excreted in breast milk. Only use NACSYS 600 mg effervescent tablets after careful consideration of the benefits and risks during 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.

Driving and using machines

There are no data available on the effect of acetylcysteine on the ability to drive. An effect is, however, unlikely.

NACSYS 600 mg effervescent tablets contain sodium

This medicine contains 115 mg sodium (main component of cooking / table salt) in each tablet. This is equivalent to 5.75% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE NACSYS 600 MG EFFERVESCENT TABLETS

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

Adults:

The recommended dose is 1 effervescent tablet once daily.

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

Dissolve the effervescent tablet in half a glass of water. Drink the solution immediately.

Do not use this medicine for longer than 14 days without consulting a doctor.

If you take more NACSYS 600 mg effervescent tablets than you should

Symptoms that may occur are: nausea, vomiting and diarrhoea. If you have taken too many NACSYS 600 mg effervescent tablets, immediately contact your doctor or pharmacist.

BACK

If you forget to take NACSYS 600 mg effervescent tablets

If you have forgotten to take a dose and it is almost time for the next dose, do not take the 'forgotten' dose, but continue the schedule as given under "How to take NACSYS 600 mg effervescent tablets." Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. 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 NACSYS 600 mg effervescent tablets and contact your doctor or go to the emergency department 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 NACSYS 600 mg effervescent tablets. You will require emergency medical care or need to be admitted to hospital.

This very serious side effect is very rare (occurs in fewer than 1 in 10,000 users). Bleedings are also very rare.

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)
- 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, 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.

Consult with your doctor or pharmacist if you notice that the effect of NACSYS 600 mg effervescent tablets is too strong or not strong enough.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 NACSYS 600 MG EFFERVESCENT TABLETS

Keep this medicine out of the sight and reach of children. Store in the original package to protect against moisture.

Shelf life

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

After first opening the product may be used for a maximum of 10 days in tubes with 10 effervescent tablets or 20 days in tubes with 20 effervescent 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 NACSYS 600 mg effervescent tablets contain

The active substance is acetylcysteine.

The other ingredients are sodium hydrogen carbonate (E500) (equivalent to 115 mg sodium), citric acid (E330), sucralose (E955), and orange flavour (contains Orange Essential Oil, Orange Essential Oil terpenless, gum arabic (E414), butylated hydroxyanisole (E320), citric acid monohydrate (E330), and maltodextrin).

What NACSYS 600 mg effervescent tablets look like and contents of the pack

NACSYS 600 mg effervescent tablets are round, flat, white to yellowish effervescent tablets. The tablets are packaged in a propylene tube with a polyethylene cap and a desiccant. Each tube contains 6, 10, or 20 effervescent tablets and are packed in cartons containing 6, 10, 12, 20 or 30 tablets. Not all pack sizes may be marketed.

You may sometimes smell a mild sulfur odour when opening the package. This is normal and harmless.

Marketing Authorisation Holder:

ALTURIX Ltd
287 Upper Fourth Street
Milton Keynes
MK9 1EH

Manufacturer:

Elara Pharmservices Limited
Iron Farm, 7 Grimesgate
Diseworth, Derby,
DE74 2QD
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherlands: Acetylcysteine Alplex 600 mg, bruistabletten
Ireland: NACSYS 600 mg effervescent tablets
United Kingdom: NACSYS 600 mg effervescent tablets

This leaflet was last revised in July 2023