

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

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1. WHAT NACSYS 600 MG EFFERVESCENT TABLETS IS AND WHAT IT IS 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 membrane in the airways), emphysema, mucoviscidosis (cystic fibrosis) and bronchiectasis (chronic widening of an airway passage).

NACSYS 600 mg Effervescent tablets is indicated only for adult.

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

Do not use NACSYS 600 mg effervescent tablets

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

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 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 adolescent 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 abovementioned warnings are apply to you, or have applied to you in the past.

Other medicines and NACSYS 600 mg effervescent tablets

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

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

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 the 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 Acetylcysteine Alpex 600 mg effervescent tablets 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.

Driving and using machines

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

Ingredients of this medicine you should take into account

This medicinal product contains 115 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE NACSYS 600 MG EFFERVESCENT TABLETS

Adults:

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.

Always use this medicine exactly as prescribed. Check with your doctor or pharmacist if you are not sure.

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

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

Symptoms that may occur are: nausea, vomiting and diarrhoea.

If you have used too many NACSYS 600 mg effervescent tablets, immediately contact your doctor or pharmacist.

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 use NACSYS 600 mg effervescent tablets".

Do not take a double dose to make up for a forgotten dose.

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 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 NACSYS 600 mg effervescent tablets. You will require emergency medical care or need be admitted to the 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace -IRL - Dublin 2

Tel: +353 1 6764971 - Fax: +353 1 6762517

Website: www.hpra.ie - e-mail: medsafety@hpra.ie

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 package after "Do not use after" or "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 tube with 10 effervescent tablets or 20 days in tube 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 contains

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 looks 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. A tablet container contains 6, 10, or 20 effervescent tablets.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

ALPEX PHARMA (IRL) Ltd

Stradbrook House, Stradbrook Road,
Blackrock, Co. Dublin
A94X9A2 - Ireland
contact@alpex.com

Manufacturer:

Kymos, S.L.

Ronda de Can Fatjó, 7B
(Parque Tecnológico del Vallès),
Cerdanyola del Vallès, 08290 Barcellona

Distributor:

HK Pharma Ltd

PO BOX 845
Bedford
MK45 9EB

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

The Netherlands: Acetylcysteine Alpex 600 mg, bruistabletten

Ireland: NACSYS 600 mg effervescent tablets

United Kingdom: NACSYS 600 mg effervescent tablets

This leaflet was last revised in 12/2020