

## Package leaflet: Information for the user

### Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets Acetylcysteine

#### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

#### **What is in this leaflet**

1. What Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets is and what it is used for
2. What you need to know before you take Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets
3. How to take Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets
4. Possible side effects
5. How to store Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets
6. Contents of the pack and other information

#### **1. What Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets is and what it is used for**

Acetylcysteine breaks down tough, sticky mucus, so that the liquid is thin and can be easily coughed up. This medicine can be used in respiratory diseases such as bronchitis, emphysema, mucoviscidose and bronchiectasis.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets is indicated for adults only.

#### **2. What you need to know before you take Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets**

##### **Do not take Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets**

- if you are allergic to acetylcysteine or any of the other ingredients of this medicine (listed in section 6).
- if your child is under 2 years of age.
- if you are a child or pregnant woman suffering from phenylketonuria.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets

- If your child is between 2 and 18 years of age. Other forms and strengths of acetylcysteine are more suitable for these patient groups.

- If you suffer from bronchial asthma, you can also suffer from bronchospasms. If this occurs, immediately stop the treatment and consult a doctor.
- If you have a history of stomach ulcers, because Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets can irritate your stomach wall. Especially if you use other medicines known to irritate the stomach wall.
- Rare cases of severe allergic reactions with (high) fever, red spotted skin, aching joints and/or eye inflammations (Stevens-Johnson syndrome) or acute hypersensitivity reactions with fever and blistering skin or shedding of skin (Lyell syndrome) which were linked to the use of Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets have been reported. In most cases at least one other medicine most likely causing the reaction was taken. If you notice new changes to your skin or mucus, immediately **stop taking acetylcysteine and seek medical advice**.
- Especially at the start of treatment, the sticky mucus can increase in volume due to the fact that it will liquify. If you are unable to cough up this liquid mucus effectively, immediately consult your doctor so that appropriate measure can be taken to remove mucus.

### **Children and adolescents**

Mucolytics, such as Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets, can block the airway of children under the age of 2 years, due to the properties of the airway in this age category. The ability to cough up mucus may be limited. Therefore, this medicine is not suitable for children under 2 years of age.

Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets should not be used in children between 2 and 18 years of age.

### **Other medicines and Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets**

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

If you are taking other medicines, do not dissolve them simultaneously with this medicine.

If you use antibiotics, it is advised to take these two hours before or after taking acetylcysteine.

Concomitant use of acetylcysteine and cough reflex muffling medicines is not allowed, because it is necessary to cough up the loosened mucus.

This medicine can strengthen the blood pressure lowering effect of nitroglycerin (medicine used against an oppressive painful sensation in the chest (angina pectoris)). Caution is advised.

When using activated carbon (a remedy for traveler's diarrhea), the effect of Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets may decline.

### **Pregnancy and 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.

#### Pregnancy

Due to the aspartame content pregnant women suffering from phenylketonuria should not use Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets.

Data about acetylcysteine use in pregnant women is limited. Animal testing have shown no or indirect harmful effects on pregnancy or the development of the child before, during and after birth. Use Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets only after careful consideration of the advantages and disadvantages during pregnancy.

#### Breastfeeding

It is unknown if acetylcysteine passes into breast milk. Use Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets only after careful consideration of the advantages and disadvantages during pregnancy.

### **Driving and using machines**

There are no data on the effect of acetylcysteine on the ability to drive. However, an effect is unlikely.

### **Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets contains sodium and aspartame**

This medicine contains 146 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 7.3% of the recommended maximum daily dietary intake of sodium for an adult. Caution is advised in patients with a controlled sodium diet.

This medicine contains 20 mg aspartame in each effervescent tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKA), a rare genetic disorder in which phenylalanine build up because the body cannot remove it properly.

### **3. How to take Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets**

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

The recommended dose for adult is 1 effervescent tablet once daily.

For patients having trouble coughing up mucus it is recommended to take the effervescent tablet in the morning.

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

Do not use for more than 14 days without consulting a doctor.

#### **Use in children and adolescents**

Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets should not be used in children under the age of 2 years.

Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets is not suitable for children and adolescents up to 18 years. Other acetylcysteine containing forms and strengths are more suitable for this patient group.

#### **If you take more Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets than you should**

Effects that may occur are nausea, vomiting and diarrhea.

Immediately contact your doctor if you take more Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets than you should.

#### **If you forget to take Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets**

If you forget to take a dose and it is almost time for your next dose, do not take the "forgotten" dose, but continue with the schedule as shown under "How to take Acetylcysteine Essential-Healthcare 600mg 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.

Immediately stop taking Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets and contact your doctor or go to the emergency department of a nearby hospital if any of the following side effects occurs:

- shock (strong decrease of blood pressure, paleness, agitation, weak pulse, clammy skin, decreased consciousness) by a sudden vasodilation resulting from severe hypersensitivity to certain substances (anaphylactic shock).
- sudden accumulation of fluid in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and / or itching and rash, often as an allergic reaction (angioedema)

Above reactions are very serious side effects. In the event that these reactions occur with you, it is possible that you have a serious allergic reaction to this drug. You may need urgent medical attention or need to be hospitalized.

This serious side effect is very rare (less than 1 in 10,000 users) for. Also bleeding are very rare.

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

- distress by cramping of the muscles in the airways (bronchospasm)
- difficult breathing, shortness of breath or difficulty breathing (dyspnea)
- indigestion with symptoms like feeling of fullness in the upper abdomen, stomach pain, belching, nausea and heartburn (dyspepsia)

These side effects are rare (affects 1 to 10 users in 10,000).

- Hypersensitivity  
This may manifest as bronchospasm and dyspnea (see above), rapid heartbeat (tachycardia), itching (pruritus), rash with intense itching and hives (urticaria) and angioedema.
- Headache
- Ringing in the ears (tinnitus)
- Stomatitis (inflammation of the mouth)
- Diarrhea
- Fever
- Lowered blood pressure
- Abdominal pain
- Nausea
- Vomiting

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

If you have a history of gastric or duodenal ulcer, acetylcysteine may have an adverse effect on your stomach mucosa.

If you get any of the side effects? Or do you have any side effects not listed in this leaflet? Please contact your doctor or pharmacist.

In case you find that the drug is too strong or too weak, talk to your doctor or pharmacist.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance.

Website: [www.hpra.ie](http://www.hpra.ie) or email [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets**

Keep this medicine out of the sight and reach of children.

Store in the original package to protect from moisture and light. Keep the tablet container well closed.

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

After first opening of the tube the medicine may be used for a maximum of 8 weeks.

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 Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets contains**

- The active substance is acetylcysteine. Each effervescent tablet contains 600 mg acetylcysteine.
- The other ingredients are citric acid (E330), sodium hydrogen carbonate (E500ii) (equivalent to 146 mg sodium), aspartame (E951) (equivalent to 11 mg phenylalanine), Povidone K-30 (E1201), sodium chloride, PEG 6000, lemon flavour (contains corn maltodextrin, flavouring preparations, flavouring substances, natural flavouring substances and alpha-tocopherol (E307)).

### **What Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets looks like and contents of the pack**

Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets are round, smooth, white effervescent tablets.

The tablets are packed in a PP tablet container with a desiccant containing PP cap in a carton box. Each container holds 10 tablets and 2 or 3 containers are packed per box.

### **Marketing Authorisation Holder and Manufacturer**

#### *Marketing authorisation holder*

Asctot Laboratories (Ireland) Limited  
The Georgian Collection  
12 Merrion Square North  
Dublin 2, D24 Y6DF  
Ireland

#### *Manufacturer:*

Basic Pharma Manufacturing B.V.  
Burgmeester Lemmensstraat 352  
6163 JT Geleen  
The Netherlands

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

The Netherlands	Acetylcysteine Birchwood 600 mg, bruistabletten
Ireland	Acetylcysteine Essential-Healthcare 600mg Effervescent Tablets
United Kingdom	AceCil 600 mg Effervescent Tablets

**This leaflet was last revised in.**