

## Package leaflet: Information for the user

### ACC Long, 600 mg effervescent tablets acetylcysteine

#### **Read all of this leaflet carefully before you start using 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.

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

1. What ACC Long is and what it is used for
2. What you need to know before you take ACC Long
3. How to take ACC Long
4. Possible side effects
5. How to store ACC Long
6. Contents of the pack and other information

#### **1. What ACC Long is and what it is used for**

ACC Long contains the active substance acetylcysteine and has a mucolytic effect in the respiratory tract.

ACC Long is used to **loosen sputum** and **relieve cough** in respiratory diseases involving **viscous mucus**.

This medicine should only be used in adults.

#### **2. What you need to know before you take ACC Long**

##### **Do not take ACC Long:**

- if you are allergic to acetylcysteine or any of the other ingredients of this medicine (listed in section 6);
- children under the age of 14 age due to the high content of the active substance.

##### **Warnings and precautions**

Ask your doctor or pharmacist for advice before taking ACC, if you have any

- **changes in the skin and mucous membranes**  
Very rare cases of severe skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome have been reported with acetylcysteine. If skin and mucous membrane changes occur, a physician should be consulted immediately and acetylcysteine discontinued.
- **bronchial asthma**
- previous or current **gastrointestinal ulcers**
- **hypersensitivity to histamine**  
Long-term treatment should be avoided in such patients as ACC affects histamine metabolism and may cause symptoms of intolerance (eg headache, runny nose, pruritus).
- **inability to cough up sputum.**

### **Other medicines and ACC Long**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially true for the following drugs:

- **cough suppressants**  
When ACC is used in combination with antitussives, a decrease in the cough reflex may result in dangerous mucus accumulation. Therefore, the prescribing of such combination therapy should be considered with particular care. Be sure to consult your doctor before using this combination.
- **antibiotics**  
Clinical studies have shown that acetylcysteine attenuates the effects of antibiotics (tetracyclines, aminoglycosides, penicillins). Therefore, antibiotics should be administered separately from acetylcysteine and at least two hours apart. This does not apply to medicines containing the active substance cefixim or loracarbef. These medicines can be taken at the same time as acetylcysteine.
- **activated carbon**
- **glyceryl trinitrate**: a medicine also known as nitroglycerin, which is used to dilate blood vessels. Your doctor will monitor you for low blood pressure, which can be severe and can cause headaches.

### **Laboratory tests**

Tell your doctor that you are taking ACC if you need the following tests, the medicine may affect the following:

- **salicylates**: medicines used to treat pain, inflammation or rheumatism,
- the presence of ketone bodies in the urine.

### **ACC Long with food and drink**

ACC Long tablets should be taken after a meal.

The effervescent tablets should be dissolved in a glass of water before use.

#### *Note*

The mucolytic (phlegm-loosening) effect of ACC Long is facilitated by the consumption of fluids.

### **Pregnancy, breast-feeding and fertility**

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.

Due to the lack of sufficient data about the use of acetylcysteine in pregnant women and breast-feeding mothers, this medicine can only be used in these situations under a doctor's order.

No data are available on the effects of acetylcysteine on human fertility.

### **ACC Long contains residues of lactose and sorbitol**

If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking this medicine.

#### *Advice for diabetics*

One ACC Long tablet contains 0.01 carbohydrate exchange units.

### **ACC Long contains sodium**

One ACC Long 600 mg effervescent tablet contains 138.8 mg of sodium (the main ingredient in table salt). This is equivalent to 6.9% of the maximum recommended daily allowance of sodium in adults.

## **3. How to take ACC Long**

Always use 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.

### For loosening phlegm (secretolysis) in the case of acute upper respiratory tract diseases:

*Adults and adolescents starting from the age of 14*

1/2 effervescent tablets of ACC Long twice a day or one effervescent tablet once a day (corresponds to 600 mg of acetylcysteine per day).

In the case of mucoviscidosis (hereditary disease)

Patients with mucoviscidosis weighing over 30 kg may use up to 800 mg of acetylcysteine per day if required.

*Duration of use*

The duration of use depends on the type and severity of the disease and is determined by a doctor.

If you feel that the effect of ACC Long is too strong or too weak, talk your doctor or pharmacist.

**If you take more ACC Long than you should**

In the case of an acetylcysteine overdose, you may develop diarrhoea, nausea and vomiting. If overdose symptoms occur, talk to a doctor.

**If you forget to use ACC Long**

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

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

**4. Possible side effects**

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

Stop taking ACC and contact your doctor if you experience any signs of allergic or severe skin reactions.

**Uncommon**, may affect up to 1 in 100 people

- **allergic reactions.**

**Very rare**, may affect up to 1 in 10,000 people

- **severe allergic reactions** up to and including shock
- **severe skin reactions** such as Stevens-Johnson syndrome and toxic epidermal necrolysis.

Other possible side effects may occur with the following frequencies:

**Uncommon**, may affect up to 1 in 100 people

- headache
- fever
- Inflammation of the lining of the mouth
- abdominal pain
- nausea, vomiting
- diarrhea
- ringing or buzzing in the ears
- accelerated heartbeat
- drop in blood pressure
- itching, hives, skin rash
- generalized rash
- mostly painful, severe swelling of the deep layers of the skin, mostly on the face.

**Rare**, may affect up to 1 in 1,000 people

- shortness of breath
- bronchospasm - in patients with predominantly hypersensitive bronchial system for bronchial asthma
- indigestion.

**Very rare**, may affect up to 1 in 10,000 people

- bleeding.

**Not known**, frequency cannot be estimated from the available data

- swelling of the face caused by excess fluid
- decreased platelet aggregation

### **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 [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store ACC Long**

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

Tubes:

Do not store at a temperature higher than 30 °C and protect from moisture and light.

After taking out a tablet, tightly seal the tube!

Sachets:

This medicine does not require any special storage conditions.

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

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 ACC Long contains**

- The active substance is acetylcysteine.
- The excipients are ascorbic acid (vitamin C), citric acid, lactose monohydrate, D-mannitol, sodium carbonate, sodium citrate, sodium cyclamate, sodium bicarbonate, saccharin sodium, dewberry fragrance (contains sorbitol).

### **What ACC Long looks like and contents of the pack**

PP tubes with a PE cap or sealed triple-layer foil (polyethylene + aluminium + paper) sachets in boxes.

The packages contain 6 or 10 effervescent tablets.

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

#### Marketing Authorisation Holder:

Sandoz d.d.

Verovškova 57

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Slovenia

#### Manufacturer:

Salutas Pharma GmbH

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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