

## Package leaflet: Information for the user

**ACC 100 mg, 100 mg powder for oral solution**

**ACC 200 mg, 200 mg powder for oral solution**

Acetylcysteine

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

Always use 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.
- 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 3 days.

### What is in this leaflet

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

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

Acetylcysteine is a derivative of the amino acid cysteine. Acetylcysteine has a phlegm-loosening effect on the bronchial region.

The ACC powder for oral solution is used for loosening phlegm.

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

##### Do not use ACC:

- if you are allergic to acetylcysteine or any of the other ingredients of this medicine (listed in section 6);
- if you have a gastric ulcer;
- children under the age of 2.

##### 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

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 with food and drink

ACC 100 mg / ACC 200 mg powder for oral solution should be dissolved in water, juice or cold tea before use.

#### Note

The mucolytic (phlegm-loosening) effect of the ACC powder for oral solution 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 100 mg and ACC 200 mg powders for oral solution contain sucrose, glucose and lactose.

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 sachet of ACC 100 mg powder for oral solution contains 0.24 carbohydrate exchange units.

One sachet of ACC 200 mg powder for oral solution contains 0.23 carbohydrate exchange units.

## 3. How to take ACC

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 is 400–600 mg of acetylcysteine per day.

For loosening phlegm in the case of acute upper respiratory tract diseases:

*for adults and adolescents over the age of 14*, 400–600 mg per day as a single dose or divided into 2–3 doses;

*for children aged 6–14 years*, 300–400 mg per day, divided into 2–3 doses;

*for children aged 2–6 years*, 200–300 mg per day, divided into 2–3 doses;

In the case of mucoviscidosis:

*for children over the age of 6*, 600 mg per day, divided into 3 doses;

*for children aged 2–6 years*, 400 mg per day, divided into 4 doses.

In patients weighing more than 30 kg, the dose may be increased to up to 800 mg per day.

*Duration of treatment:* In the case of acute diseases, 5–7 days; in the case of chronic bronchitis and mucoviscidosis, the treatment must last longer for prophylactic treatment of the infection.

If you feel that the effect of the ACC powder for oral solution is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more ACC 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 take ACC**

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

#### **If you stop taking ACC**

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.

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**

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

Do not store at a temperature higher than 25 °C.

Do not use this medicine after the expiry date which is stated on the carton. 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 contains**

- The active substance is acetylcysteine.
- The excipients are ascorbic acid, saccharine, sucrose, orange flavoring (contains lactose and glucose).

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

White to yellowish partly lumpy powder with orange scent.

Original packages containing 20 sachets.

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

Marketing Authorisation Holder:

Sandoz d.d.

Verovškova 57

1000 Ljubljana

Slovenia

Manufacturer:

Salutas Pharma GmbH

Otto-von-Guericke-Allee 1

D-39179 Barleben

Germany

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

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**This leaflet was last revised in May 2020.**