



# ACC® long

## Effervescent Tablets

### Directions for Use

Dear Patient,  
Please read this package insert carefully, because it contains important information on what you should consider when using this medication. If you have any questions, please consult your doctor or pharmacist.

### ACC® long Effervescent Tablets

Active Ingredient: N-acetylcysteine

### Composition:

Active ingredient:  
One effervescent tablet contains 600 mg N-acetylcysteine.

### Additional ingredients:

Ascorbic acid (vitamin C), citric acid, lactose, mannitol, sodium citrate, sodium hydrogen carbonate, sodium carbonate, sodium cyclamate, saccharin sodium, aromatics

### Advice to Diabetics

One effervescent tablet contains 0.01 carbohydrate exchange units.

### Pharmaceutical Forms and Contents

Original packages containing  
10, 20, 50 and 100 effervescent tablets

ACC® long is administered in cases of respiratory tract diseases accompanied by severe mucous secretion (expectorant).

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### Indications:

For mucolytic therapy in cases of acute and chronic diseases of the bronchi and the lung accompanied by viscous mucus.

### Contraindications:

#### When must you not take ACC® long?

You must not take ACC® long in cases of known hypersensitivity to the active ingredient N-acetylcysteine or to one of the other ingredients.

#### What must you take into account during pregnancy/ the lactation period?

Up to now there is no sufficient data available concerning administration of N-acetylcysteine during pregnancy and the lactation period. Therefore, ACC® long should not be used during pregnancy and the lactation period except your doctor decides that the administration of ACC® long is absolutely necessary.

#### What must be taken into account in children?

ACC® long is not suitable for children of less than 14 years of age due to the high content of active agent. For this purpose, preparations with a lower content of active agent are available.

N-acetylcysteine may only be administered to babies and infants of less than 1 year of age if a vital reason was found by a doctor (vital indication). Treatment then has to be effected under strictest medical monitoring. There is no meaningful data about the dosage of N-acetylcysteine in newborn babies up to now.

### Precautionary Measures for Usage and Warnings

**What must you consider when driving vehicles and operating machinery as well as when working in an unsafe posture (e.g. climbing ladders)?**

Nothing in particular is to be considered.

### Drug Interactions with other Medications

**Which drug interactions between ACC® long and other medications must be considered?**

Medications for the treatment of bacterial infections (antibiotics)

The intake of the antibiotic tetracycline hydrochloride has to be carried out separately and at intervals of at least 2 hours (this does not apply to doxycycline).

Cough-relieving medications (antitussives)

The combined administration of ACC® long and cough-relieving preparations (antitussives) can cause a dangerous congestion of secretion due to the reduced cough reflex. Therefore, please ask your doctor before taking a cough-relieving medication in addition to ACC® long.

Nitroglycerin

Concurrent administration of ACC® long may possibly lead to an enhancement of the vasodilating and haemodiluting effect of glycerol trinitrate (nitroglycerin).

Please note that this data may also applies to medications recently used.

### Dosage Directions, Mode and Duration of Administration:

The following directions apply as far as your doctor has not prescribed ACC® long in another dosage regimen. Please keep to the directions for use, otherwise ACC® long cannot act in the right way.

#### How many effervescent tablets and how often should you take ACC® long?

Adults and adolescents from 14 years of age are to take 1 effervescent tablet once daily (600 mg N-acetylcysteine/day).

#### How and when should you take ACC® long?

The effervescent tablets are to be dissolved in a half glass of water, and the solution is to be drunk after meals.

### Notes

The mucolytic effect of ACC® long is supported by fluid intake.

The ready-for-use solution should be drunk soon after dissolving the effervescent tablets. In exceptional cases, the ready-for-use solution can be left for approximately 2 hours or kept warm due to the stabilizer ascorbic acid (vitamin C).

### Overdosage and other Mistakes in Dosage

#### What has to be done if ACC® long was taken in too high quantities (intentional or inadvertent overdosage)?

In cases of intentional or inadvertent overdosage, local irritant effects such as diarrhoea, vomiting, pain in the stomach, heartburn and nausea may occur. Severe side effects or symptoms of intoxication have not been reported even in cases of extreme overdosage. Please consult a doctor in such a case.

#### What must you heed if you have taken too little ACC® long or if you have forgotten the intake?

If you have once forgotten the intake of ACC® long or if you have taken too little, please continue with the administration of ACC® long for the next time as prescribed in the dosage directions.

### Side effects

#### Which side effects may occur with the administration of ACC® long?

In isolated cases, diarrhoea, vomiting, heartburn and nausea may occur.

The occurrence of headaches, inflammations of the mucous membrane in the mouth (stomatitis) and a noise in the ear (tinnitus) has been reported in rare cases.

According to reports of individual cases, allergic reactions have been observed after administration of N-acetylcysteine such as drop in blood pressure, difficult breathing (bronchospasm), skin eruption (exanthema, rash), itching, accelerated heart rate (tachycardia) and wheals (urticaria).

The bronchospasms, which were observed in isolated cases, occurred mainly in patients with hyperreactive bronchial system in connection with bronchial asthma, so-called "hyper-responders" (increased sensitivity of the bronchi towards various irritations)

The occurrence of bleeding in connection with the administration of N-acetylcysteine has been reported in individual cases, partially in the scope of hypersensitivity reactions.

If you observe side effects not listed in this package insert, please inform your doctor or pharmacist.

#### Which countermeasures have to be taken in case of side effects?

The administration of ACC® long must not be continued when first symptoms of a hypersensitivity reaction occur.

Inform your doctor, so that he/she can decide on the degree of severity and, if necessary, on further measures which are required.

### Details and Notes Concerning the Shelf Life of the Drug

The expiry date of the drug is printed on the package. Do not use the medication after this date!

#### How is ACC® long to be stored?

Store at a dry place! Protect from light!  
After taking out tablets, please close tablet tube tightly again.

### Last Update of Information

September 2001

#### (This is a medicament)

- Medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep Medicament out of reach of children.

Council of Arab Health Ministers  
and Union of Arab Pharmacists

Please keep this medicine out of the reach of children!