

**ACETIN<sup>®</sup> / ACETIN<sup>®</sup> 200****DESCRIPTION**

Orange granular powder

**COMPOSITION**

Each sachet of ACETIN<sup>®</sup> 5 g powder contains Acetylcysteine 100 mg and each sachet of ACETIN<sup>®</sup> 200 5 g powder contains Acetylcysteine 200 mg.

**PHARMACODYNAMICS****Actions:**

The mucolytic action of acetylcysteine is related to the sulfhydryl group in the molecule, which acts directly to split disulfide linkages between mucoprotein complexes, resulting in depolymerization and a decrease in mucus viscosity. Its action is unaffected by the presence of DNA. The mucolytic activity of acetylcysteine increases with increasing pH. Significant mucolysis occurs between pH 7 and 9.

**PHARMACOKINETICS**

Acetylcysteine reduces the viscosity of purulent and non-purulent pulmonary secretions and facilitates their removal by coughing, postural drainage, or mechanical means. Following oral inhalation or intratracheal instillation. Most of the administered drug appears to participate in the sulfhydryl disulfide reaction the remainder is absorbed from the pulmonary epithelium, deacetylated by the liver to cysteine, and subsequently metabolized. Following oral administration (e.g., when used as an antidote for acetaminophen overdose), acetylcysteine is absorbed from the GI tract.

**INDICATIONS**

Mucolytic; adjuvant therapy for abnormal, viscid or inspissated mucus secretion in chronic bronchopulmonary disease (chronic emphysema, emphysema with bronchitis, chronic asthmatic bronchitis, tuberculosis, bronchiectasis). Antidote for acetaminophen overdose.

**CONTRAINDICATIONS**

Acetylcysteine is contraindicated in those patients who are sensitive to it.  
Contraindicated in children under 2 years of age.

**WARNINGS & PRECAUTIONS****General:**

After proper administration of Acetylcysteine, an increased volume of liquefied bronchial secretions may occur. When cough is inadequate, the airway must be maintained open by mechanical suction if necessary. When there is a mechanical block due to foreign body or local accumulation, the airway should be cleared by endotracheal aspiration, with or without bronchoscopy. Asthmatics under treatment with Acetylcysteine should be watched carefully. Most patients with bronchospasm are quickly relieved by the use of a bronchodilator given by nebulization. If bronchospasm progresses, the medication should be discontinued immediately.  
This product contains Aspartame, unsuitable for phenylketonurics.

**INTERACTIONS WITH OTHER MEDICAMENTS**

Activated charcoal should be avoided in the treatment of Acetaminophen overdose since they may decrease the absorption of orally administered Acetylcysteine.

**ADVERSE EFFECTS / UNDESIRABLE EFFECTS**

Adverse effects have included stomatitis, nausea, vomiting, fever, rhinorrhea, drowsiness, clamminess, chest tightness, and bronchoconstriction. Clinically overt Acetylcysteine induced bronchospasm occurs infrequently and unpredictably even in patients with asthmatic bronchitis or bronchitis complicating bronchial asthma. Acquired sensitization to Acetylcysteine has been reported rarely. Reports of sensitization in patients have not been confirmed by patch testing. Sensitization has been confirmed in several inhalation therapists who reported a history of dermal eruptions after frequent and extended exposure to Acetylcysteine. Reports of irritation to the tracheal and bronchial tracts have been received and although hemoptysis has occurred in patients receiving Acetylcysteine such findings are not uncommon in patients with bronchopulmonary disease and a causal relationship has not been established.

**Immune System Disorders:**

Anaphylactic / anaphylactoid reaction

**Skin and Subcutaneous Tissue Disorders:**

Severe cutaneous adverse reactions (SCAR) e.g. erythema multiforme, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). In most of these cases reported at least one other drug was administered at the same time, which may have possibly enhanced the described mucocutaneous effects.

**DOSAGE AND ADMINISTRATION**

**For ACETIN<sup>®</sup> (100 mg):** Dissolve 1 sachet in a half glass of water.

Adults and Children above 6 years of age: 2 sachets 3 times a day.

Children 2-6 years of age : 2 sachets 2 times a day.

**For ACETIN<sup>®</sup> 200 :** Dissolve 1 sachet in a half glass of water.

Adults and children above 6 years of age: 1 sachet 2-3 times a day.

Children 2-6 years of age : 1 sachet 2 times a day.

As antidote for acetaminophen overs dosage : A loading dose of 140mg/kg should be administered orally as soon as possible, followed by oral maintenance doses of 70 mg/kg every 4 hours for 17 additional doses.

**SYMPTOMS AND TREATMENT OF OVERDOSAGE**

Acetylcysteine overdose may result in exaggerated side effects. Treatment is supportive and symptomatic.

**STORAGE CONDITIONS**

Store below 30°C. Protect from light.

**SHELF LIFE**

3 years

**AVAILABLE PACK SIZE**

A box of 50 sachets of 5 g powder per sachet

**DATE OF REVISION OF PACKAGE INSERT**

April 2018

Manufactured by

**L.B.S. LABORATORY LTD., PART.**

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Product Registration Holder

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18 cm

Code: R 053/18  
 Project: Acetin 100, 200 (Pow)  
English LF (311)  
 Date: 02-05-2018  
 Printed Size: 12.7x18 cm (WxH)  
 Print Colours:  
 Process Colours: CMYK  
 Special Colours: **K = 100**