YUAN CHOU CHEMICAL & PHARMACEUTICAL CO., LTD
No. 272 , Nangang 3rd Rd., Nantou City , Nantou County 54067, Taiwan R.O.C

Package Insert

1. Name of the medicinal product

Medicare Acetylcysteine 600 mg granules

2. Qualitative and quantitative composition

Each sachet (3g) contains Acetylcysteine 600 mg

3. Product Description

White granules with a sweet and sour taste and a sulfur odor.

4. Clinical particulars

4.1 Therapeutic indications

All respiratory tract diseases leading to the formation of thick secretions difficult to be expectorated, such as acute and chronic bronchitis, laryngitis, sinusitis, tracheitis, influenza, bronchial asthma and (as complementary treatment) mucoviscidosis.

4.2 Posology and method of administration

Usual posology for acute diseases:

Adolescents over 12 years of age and Adults : One 600 mg sachet daily,

Long-term treatment: 400-600 mg daily, divided into one or more administrations, with a maximum treatment duration of 3 - 6 months.

If the excessive mucus production and the consequent cough do not disappear after a two-week treatment, the diagnosis should be re-evaluated in order to exclude a possible malignant disease of the respiratory tract.

Mucoviscidosis: the same dosage as above, however, for children from 6 years of age, 200mg 3 times daily or 600 mg once daily.

Instruction for Use:

Dissolve the content of one sachet into a glass of cold or warm water.

4.3 Contraindications

Known hypersensitivity to acetylcysteine or to any of the excipients. Contraindicated in children below two (2) years of age. Active peptic ulcer.

4.4 Special warnings and precautions for use

Caution is advised in patients with a history of peptic ulcer, especially when used concomitantly with other medicinal products known to irritate the mucous membrane of the gastrointestinal tract and acetylcysteine can induce vomitting.

Bronchospasms may occur with the use of acetylcysteine especially in patients with asthma. If bronchospasms occur, the medicinal product should be discontinued immediately.

Bronchial secretions may become more fluid and increase in volume, in particular at the start of the treatment with acetylcysteine. When a patient is unable to cough up the secretions effectively, postural drainage and bronchoaspiration should be performed.

Caution should be used in patients with histamine intolerance.

Paediatric population：

Mucolytic drugs may obstruct the airways of children under 2 years of age, due to the physiological characteristics of the airways in this age group. The ability to cough up mucus may be limited. Therefore, mucolytic drugs should not be used in children under 2 years of age.

The safety and efficacy is not established in children aged 2 years and older and adolescents.

A mild sulfur odour does not indicate a change in the medicinal product, but is a property of the active substance itself.

WARNING : Unsuitable for phenylketonurics.
Medicare Acetylcysteine 600 mg granules may cause severe allergy and serious skin reactions. Stop using Medicare Acetylcysteine 600 mg granules and seek medical assistance immediately if you experience any of the following symptoms:
• Severe allergy: breathing difficulties, light headedness, skin swellings or rash.
• Severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation

4.5 Interaction with other medicinal products and other forms of interaction

Activated charcoal in case of intoxication can decrease the effect of acetylcysteine due to reduced absorption.

To date, the inactivation of antibiotics by acetylcysteine has been reported only in in-vitro tests, whereby the relevant substances were mixed directly with each other. However, if oral antibiotics are required, it is advised that these should be taken two hours before or after Acetylcysteine.

Acetylcysteine may enhance the vasodilatory and inhibiting thrombocytes aggregation effects of glyceryl trinitrate. The co-administration of acetylcysteine and carbamazepine may result in subtherapeutic carbamazepine concentrations

Acetylcysteine should not be administered concomitantly with antitussive medicinal products

Interactions with laboratory tests:

Acetylcysteine may have an effect on the values of salicylates by colorimetric analysis.

4.6 Pregnancy and Lactation

Pregnancy:

Data from a limited number of exposed pregnant women showed no adverse events on pregnancy or the health of the foetus or the newborn. No experience from epidermiological studies is available. Animal studies do not indicate direct or indirect toxicity with any effect on pregnancy, embryonic development, development of the foetus and/or postnatal development. Caution is indicated when used in pregnancy.

Lactation:

There are no studies showing whether acetylcysteine passes into human breast milk. Medicare Acetylcysteine 600 mg granules should not used during breastfeeding, unless absolutely necessary.

4.7 Effects on ability to drive and use machines

There are no data on the effect of acetylcysteine on the ability to drive.

4.8 Undesirable effects

The table below lists the undesirable effects recorded after systemic use of oral acetylcysteine according to system/organ class.

System/organ class	Undesirable effect			
	Uncommon (≥ 1/1,000 to <1/100)	**Rare** (≥ 1/10.000 to <1/1,000)	**Very rare** (<1/10,000)	**Not known**
Immune system disorder	Hypersensitivity*		Anaphylactic shock, anaphylactic/anaphylactoid reactions	
Nervous system disorders	Headache			
Ear and labyrinth disorders	Tinnitus			
Vascular disorders			Haemorrhages	
Gastrointestinal disorders	Stomatitis, abdominal pain, nausea, vomiting, diarrhoea	Dyspepsia		
Skin and subcutaneous tissue disorders				Facial oedema
General disorders and administration site conditions	Pyrexia			
Investigations	Low blood pressure			

A decrease in platelet aggregation in the presence of acetylcysteine has been confirmed in various studies. The clinical significance of this has not been determined.

*Hypersensitivity reactions include bronchospasm, dyspnoea, pruritus, urticaria, rash, angioedema and tachycardia.

In patients with a peptic ulcer or peptic ulcer history, acetylcysteine may have an unfavourable effect on the gastric mucosa.

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.

4.9 Overdose

To date no toxic overdose has been observed for the oral pharmaceutical forms of acetylcysteine. Healthy voluntary study subjects were treated for three months with a dose of 11.6 acetylcysteine per day without any serious undesirable effects being observed.

Oral doses of up to 500 mg acetylcysteine per kg body weight were tolerated without any signs of intoxication. Overdoses may lead to gastrointestinal effects such as nausea, vomiting and diarrhoea. Therapeutic measures in case of over dose are symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mucolytics. ATC-code: R05C B01

Mechanism of action /Pharmacodynamic effects

Acetylcysteine is a mucolytic.
The mucolytic action is mediated by a reduction in the viscosity of bronchial mucus. This is explained by the depolymerisation with the disulfide bridges between the macromolecules in the mucus being opened.

In addition, acetylcysteine is a precursor of glutathione. Acetylcysteine is a derivative of the natural amino acid cysteine, which serves as a substrate for the synthesis of glutathione in the body.

Apart from the fact that acetylcysteine is able to normalise a state of glutathione depletion, it is able to conjugate with various toxic compounds.

5.2 Pharmacokinetic properties

Absorption / Distribution

Acetylcysteine is rapidly absorbed after oral administration and distributed throughout the organism. The highest tissue concentrations are reached in the liver, kidneys and lungs.

Biotransformation / Elimination

Acetylcysteine is mainly deacetylated to cysteine in the liver. Most of this is processed in the amino acid metabolism. Moreover, it forms reversible disulfide compounds with amino acids and proteins with free sulfydryl groups. Finally, high doses are largely converted into inorganic sulfate, which undergoes renal excretion.

5.3 Preclinical safety data

Preclinical data of acetylcysteine based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction do not indicate a risk to humans.

6. Pharmaceutical particulars

6.1 List of excipients

Sorbitol、Aspartame、Orange flavor、Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in the original package to protect against moisture. Store below 30°C.

6.5 Nature and contents of container

Each aluminium foil sachet (3g) contains Acetylcysteine 600 mg.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Name and Address of Manufacturer

Yuan Chou Chemical and Pharmaceutical Co. Ltd.

No. 272, Nangang 3rd Rd, Nantou City, Nantou County 54067, Taiwan.

8. Name and Address of Product Registration Holder

World Medicare Supplies Sdn Bhd

PT 5740(1st Floor),Jalan TS 2/1E,

Taman Semarak 2,71800 Nilai Negeri Sembilan, Malaysia.

9. Date of Revision of PI

September 2026