MUCIL 100 & MUCIL 200

CONTENTS
MUCIL 100: Each ***5 grams*** sachet contains 100 mg acetylcysteine.
MUCIL 200: Each ***3 grams*** sachet contains 200 mg acetylcysteine.

DESCRIPTION
Orange granules.

INDICATIONS
MUCIL 100 / MUCIL 200 is indicated as mucolytic agent in pathological respiratory conditions associated with intense secretion of hyperviscous mucus.

RECOMMENDED DOSAGE
Adults
1 sachet of **MUCIL 200** or 2 sachets of **MUCIL 100**, 2 to 3 times a day.
For prevention of exacerbation, the use of **MUCIL 200** is recommended.

Children
2 to 12 year old: one sachet of **MUCIL 100** 3 times daily or one sachet of **MUCIL 200** twice daily.

The duration of treatment should be 5 to 10 days in acute treatment, and in chronic states, the treatment may be continued for several months as according to the doctor / physician's advice.

METHOD OF ADMINISTRATION
Dissolve the contents of sachet(s) in a glass of water and drink immediately. Avoid using a metal container.

CONTRAINDICATIONS
MUCIL 100 / MUCIL 200 is contraindicated:
- in patients who are sensitive to acetylcysteine or any of the ingredients in the formulation
- in children under 2 years of age
- severe asthma exacerbation
- chronic duodenal and gastric ulcer disease.

PRECAUTIONS / WARNINGS
- The occurrence of severe skin reactions such as Steven-Johnson syndrome and Lyell's syndrome has very rarely been reported in temporal connection with the use of acetylcysteine. If cutaneous and mucosal changes newly occur, medical advice should be sought without delay and use of acetylcysteine be terminated.
- Care during use in patients with bronchial asthma and in patients with anamnestic ulcers.
- Caution is advised in patients with histamine intolerance. Longer term therapy should be avoided in these patients, as Acetylcysteine has an effect on histamine metabolism and may lead to symptoms of intolerance (e.g. headache, vasomotor rhinitis, itching).
- Administration of **MUCIL 100 / MUCIL 200**, especially at the beginning of treatment, may liquefy bronchial secretions and, at the same time, increase their volume. If the patient is unable to expectorate efficiently, to avoid retention of secretions postural drainage and tracheal suction should be used.
- There are no studies on the efficacy and safety of acetylcysteine 200 mg three times daily in adolescent population.
- **MUCIL 200** contains aspartame, which is a source of phenylalanine. This may be harmful to people with phenylketonuria.
- This medicine contains a colouring agent called sunset yellow, which may cause allergic reactions.
- Acetylcysteine can cause interference with the colorimetric assay method for the determination of salicylates.
- Acetylcysteine can interfere with tests for ketones in urine.

DRUG INTERACTION
- Antitussive drugs and acetylcysteine should not be administered concomitantly because reducing the cough reflex may lead to a build-up of bronchial secretions.
- Activated charcoal may reduce the effect of acetylcysteine.
- It is advisable not to mix **MUCIL 100 / MUCIL 200** with other medicinal products.
- *In vitro* tests have shown that when antibiotics (tetracycline, aminoglycosides, penicillins) and acetylcysteine are mixed, there is a degree of antibiotic inactivation. It is precautionary to advise the administration of oral antibiotics at least 2 hours before or after acetylcysteine. This does not apply to cefixime and loracarbef.
- Co-administration of acetylcysteine can result in an enhancement of vasodilator and antiplatelet effects of glyceryl trinitrate (nitroglycerin). If concurrent administration of nitroglycerin and acetylcysteine is required, patients should be monitored and warned for hypotension that can be severe and accompanied by a headache.

PREGNANCY AND LACTATION
Pregnancy
No adequate and well-controlled studies have been done in pregnant women. Therefore, **MUCIL 100 / MUCIL 200** should be used during pregnancy only when clearly needed.

Lactation
It is not known whether or not acetylcysteine passes into breast milk. Until more data is available, use in caution when considering the use of **MUCIL 100 / MUCIL 200** in lactating women.

SIDE EFFECTS

System organ class	Frequency	Preferred term
Immune system disorders	Uncommon	Hypersensitivity
	Very Rare	Anaphylactic shock, anaphylactic / anaphylactoid reaction
Nervous system disorders	Uncommon	Headache
Ear and labyrinth disorders	Uncommon	Tinnitus
Cardiac disorders	Uncommon	Tachycardia
Vascular disorders	Uncommon	Hypotension
	Very rare	Haemorrhage
Respiratory, thoracic and mediastinal disorders	Rare	Bronchospasm, dyspnoea
Gastrointestinal disorders	Uncommon	Vomiting, diarrhoea, stomatitis, abdominal pain, nausea
	Rare	Dyspepsia
Skin and subcutaneous tissue disorder	Uncommon	Urticaria, rash, angioedema, pruritus, severe cutaneous adverse reactions (SCAR) e.g. erythema multiforme, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) – *see below for full*

		information
General disorders and administration site conditions	Uncommon	Fever
	Not known	Oedema of the face

The occurrence of serious skin reactions such as Steven-Johnson syndrome and toxic epidermal necrolysis have been reported in temporal association with the use of acetylcysteine. In most of these cases reported, at least one other drug was administered at the same time, which may be possibly enhanced the described mucocutaneous effects.

In case of the recurrence of skin and mucosal lesions, medical advice should be sought at once and the use of acetylcysteine should be terminated immediately.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE
There is a theoretical risk of hepatic encephalopathy. However, treatment is symptomatic and general supportive measures should be carried out.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
MUCIL 100 / MUCIL 200 has no known effect on the ability to drive and use machines.

PHARMACODYNAMICS
N-acetyl-L-cysteine (NAC) or acetylcysteine exerts a mucolytic-fluidizing action on mucous and mucopurulent secretions by depolymerizing the mucoprotein complexes and the nucleic acids which confer viscosity to the vitreous and purulent component of the sputum and other secretions.

Furthermore, acetylcysteine exerts a direct antioxidant action, having a free thiol (-SH) nucleophilic group that is able to interact directly with electrophilic groups of oxidant radicals. The recent finding shows that acetylcysteine protects α1-antitrypsin enzyme inhibiting elastase from inactivation by hypochlorous acid (HOCl), a powerful oxidant agent produced by the myeloperoxidase enzyme of activated phagocytes. Due to its molecular structure, acetylcysteine can readily cross cell membranes. Inside the cell, NAC is deacetylated to L-cysteine, an amino acid essential for glutathione synthesis (GSH).

GSH is a highly reactive tripeptide found ubiquitously in the various tissues of animals and is essential for the maintenance of functional capacity as well as morphological integrity. It is the most important protective intracellular mechanism against oxidant radicals, both exogenous and endogenous, as well as toward numerous cytotoxic substances. These features make **MUCIL 100 / MUCIL 200** particularly suitable for the treatment of acute and chronic affections of the respiratory system, characterised by thick, viscous mucous and mucopurulent secretions.

There is no evidence on the efficacy and safety of mucolytics including acetylcysteine in acute bronchitis.

PHARMACOKINETICS
Absorption
Following oral administration, acetylcysteine is rapidly and almost completely absorbed and metabolised in the liver to cysteine (the pharmacologically active metabolite), diacetylcysteine, cysteine and further mixed disulphides.

Distribution
Due to the high first-pass effect, the bioavailability of orally administered acetylcysteine is very low (approximately 10%). In human, maximum plasma concentrations are achieved after 1 – 3 hours with maximum plasma concentration of metabolite cysteine in the range of approximately 2 μmol/l. The protein binding of acetylcysteine was determined to be about 50%.

Biotransformation
Acetylcysteine and its metabolites occur in three different forms: partially in free form, partially bound to proteins via liable disulphide bonds and partially as incorporated amino acid. Acetylcysteine is excreted almost exclusively in the form of inactive metabolites (inorganic sulphates, diacetylcysteine) via the kidneys. The plasma half-life of acetylcysteine is approximately 1 hour and mainly determined by the rapid hepatic biotransformation. Impaired hepatic function therefore leads to prolonged plasma half-lives of up to 8 hours.

Elimination
The elimination half-life after intravenous administration is 30 – 40 minutes while excretion follows three-phase kinetics (alpha, beta and terminal gamma phase).

Acetylcysteine crosses the placenta and is detected in cord blood. No information is available regarding excretion in breast milk. No knowledge is available concerning the behaviour of acetylcysteine at the blood-brain barrier in humans.

EXCIPIENTS
MUCIL 100: Dextrose anhydrous, sunset yellow, citric acid, saccharin sodium, orange powder, orange oil, sucrose

MUCIL 200: Dextrose anhydrous, sunset yellow, citric acid, aspartame, orange powder, orange oil, sucrose

PACKING / PACK SIZES
MUCIL 100: Packed in aluminium sachet of 5g each.
MUCIL 200: Packed in aluminium sachet of 3g each.

Both **MUCIL 100 & MUCIL 200** are supplied in paper box of 30 sachets each.

STORAGE CONDITIONS
Do not store above 30°C.
Protect from moisture and light.
Keep out of reach of children.
Jauhi daripada kanak-kanak.

Shelf life: Please refer to outer box label.

Manufactured by:
T.O. PHARMA CO. LTD.
101 Soi Ladprao 124 (Sawatdikan),
Ladprao Road, Phlapphla, Wangthonglang,
Bangkok 10310, Thailand.

Revision date: April 2025