# Stenac Granules 100 mg

**Formulation:**

Each sachet contains 100mg of Acetylcysteine.

**Product Description:**

Orange granules with orange flavor. Place 1 sachet in 100 mL of hot water, and stir until the granules dissolve completely. The color of solution is light orange and clear.

**Pharmacodynamics and Pharmacokinetics:**

The N-acetylcysteine (NAC) is the N-acetyl derivative of the naturally occurring amino acid I-cysteine. NAC has an intense fluidifying action, through its free sulfydryl group, on the mucoid or mucopurulent secretions by cleaving the intramolecular and intermolecular disulfide bonds in glycoprotein aggregates.

NAC is stable in simulated gastric and intestinal fluid, is rapidly absorbed after oral administration, and distributed to body tissues including the lung.

Acute toxicity, chronic toxicity, teratology and reproduction studies support oral NAC safety. Coagulation parameters, platelet aggregation, immunoglobulins (serum and sputum lgA), hematological, hepatic and renal laboratory indices remained unchanged after oral NAC administration.

**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.

**Recommended Dosage:**

Usual posology for acute diseases

Adults: 600 mg daily, divided into one or more administrations (e.g. 200 mg sachets 3 times daily).

Adolescents over 12 years of age: 600 mg daily, divided into one or more administrations (e.g. 200 mg sachets 3 times daily).

Children from 2 to 12 years of age: one 100 mg sachet 3 times daily or 200 mg twice daily.

Special posologies

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.

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

Effects of food on drug absorption are unknown. Therefore no recommendations on taking Stenac Granules before or after meals can be made.

**Route of Administration:**

For oral use.

**Contraindication:**

Known hypersensitivity to acetylcysteine or to any of the excipients.

Contraindicated in children below two (2) years of age.

**Warnings and Precautions:**

Patients suffering from bronchial asthma must be strictly controlled during the therapy: should bronchospasm occur, the treatment should be immediately discontinued and appropriate therapeutic measures taken, as necessary.

Special caution should be taken in patient suffering from or with a history of peptic ulcer as orally administered acetylcysteine may induce vomiting.

Caution is required in patients with histamine intolerance.

It is recommended not to mix other drugs with the Stenac Granules solution.

**Interaction with Other Medicaments:**

Charcoal: (Moderate) Administration of activated charcoal and oral acetylcysteine at the same time may cause a reduction in acetylcysteine (NAC) absorption. There are conflicting data as to whether the reduced bioavailability of NAC is clinically significant during the treatment of drug overdoses. In the case of a mixed drug overdose activated charcoal may be indicated for use along with NAC. However, if

activated charcoal has been administered, lavage before administering oral NAC treatment. Activated charcoal adsorbs acetylcysteine in vitro and may do so in patients and thereby may reduce its effectiveness.

**Pregnancy and Lactation:**

Pregnancy

The available data on a limited number of exposed pregnancies indicate no adverse effects on pregnancy or on the health of the fetus or new-born child.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal, fetal and/or postnatal development.

Caution should be exercised when prescribing to pregnant women.

Lactation

No studies concerning acetylcysteine excretion into maternal breast milk are available. Stenac Granules should not be used during breastfeeding, unless clearly necessary.

**Side Effects:**

Like all medicines, Stenac has the potential to cause side effects, although not everyone will experience them. Some of the side effects of this product is listed below:

- Inflammation of the mouth and lips.
- Nausea and vomiting.
- Fever.
- Watery eyes or nose.
- Drowsiness.
- Chest tightness.
- Narrowing of the airways, leading to difficulty in breathing.
- 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.

If you experience any of these side effects or effects which are not listed, discontinue the use of this product and seek medical attention immediately.

**Symptoms and Treatment of Overdose:**

Treatment of overdose is to be symptomatic and supportive treatment as indicated by the patient's clinical condition.

**Effects on Ability to Drive and Use Machine**

Acetylcysteine has no known influence on the ability to drive and use machines.

**Storage Condition:**

Store at temperatures not exceeding 30 ˚C.

**Dosage Forms and packaging available:**

Box of 30 sachets x 1.5 g. (Acetylcysteine 100 mg, excipients q.s. 1.5g)
Granules for Oral Solution.

**Manufactured by:**

**U-Liang Pharmaceutical Co., Ltd.**
No.10, Kuang-Fu Rd., Hu-Kou Hsiang, Hsin Chu Hsien, Taiwan, R.O.C.

**Product Registration Holder:**

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Material Code