

PATIENT INFORMATION LEAFLET

- (a) Name of Product: **Stenac Granules 100mg/sachet**
- (b) Description of Product
- Description of the appearance of the product: Orange granules with orange flavor.
 - List of excipients: Dextrose Anhydrous, Saccharin Sodium, Sunset Yellow FCF, and Orange Powder.
- (c) What is the medicine?
This product can thin or dissolve thick lung mucus with active ingredient of acetylcysteine and the dosage form is granule.
- (d) Name and strength of active ingredient
Each sachet contains: Acetylcysteine 100 mg
- (e) What is this medicine used for?
Reduce the viscosity of the secretion from respiratory tract.
- (f) How much and how often should you use this medicine?
Adults and children above 6 years
– 2 sachets Stenac Granules 100mg, 2-3 times a day;
Children (2-6 years of age)
– 1 sachet Stenac Granules 100 mg from 2 to 4 times a day, according to the age. The duration of treatment should be 5 to 10 days in the acute treatment, whereas it may be continued in the chronic states for several months, according to the advice of the physician.

MODALITY OF USE

Dissolve the contents of the sachets in a glass containing a small quantity of water, mixing it, if necessary, with a spoon. A palatable solution is thus obtained, to be drunk immediately.

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

It is advisable to administer antibiotics 2 hours apart from Acetylcysteine.

- (g) When should you not take this medicine?
Do not use it if you had an allergic reaction to acetylcysteine or to any of the excipients.
Children under 2 years of age.
- (h) Undesirable effects/side effects
Like all medicines, Stenac granules can cause side effects, although not everybody gets them.
- In very rare cases, severe allergic reactions may occur such as anaphylactic shock and severe skin reaction.
- In rare cases the oral administration can be followed by shortness of breath, upset stomach and difficulty in breathing (bronchospasm).
- The most frequent side effects are headache, increased heart rate, inflammation of the mouth (stomatitis), itching (pruritus), hives (urticaria), nausea, vomiting, abdominal pain, fever, decrease in the blood pressure, diarrhoea and noises in the ears.
- If you get any side effects, talk to your doctor or pharmacist.
- (i) What other medicine or food should be avoided whilst taking this medicine?
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, cough suppressants as their ability to reduce cough reflex may lead to the accumulation of bronchial secretions.

- (j) What should you do if you miss a dose?
- ✓ If you forget to take a dose, take it as soon as possible. Take the next dose at the correct time, in accordance with the instructions given by your doctor.
 - ✓ However, if it is almost time to take the next dose, do not take the dose you have missed; only take the next dose as normal.
 - ✓ Do not take a double dose to make up for a forgotten dose.
 - ✓ If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
- (k) How should you keep this medicine?
- Store below 30°C
- (l) Signs & symptoms of overdose
- If you have taken more Stenac Granules than you should, you might experience nausea, vomit or diarrhoea. Contact your doctor.
- (m) What to do when you have taken more than the recommended dosage?
- Contact your doctor or pharmacist for further advice if you feel the symptoms or signs mentioned in section (l).
- (n) Name of manufacturer/importer/product registrant
- ✓ Product importer: Goldplus Universal PTE Ltd
 - ✓ Product registrant: Goldplus Universal PTE Ltd
 - ✓ Product owner: Synmosa Biopharma Corporation
 - ✓ Product manufacturer: U-liang Pharmaceutical Co., Ltd.
- (o) Care that should be taken when taking this medicine?
- Mucolytic agents can induce respiratory obstruction in children under 2 years of age. Due to the physiological characteristics of the airways in this age group, the ability to expectorate may be limited. Therefore mucolytic agents should not be used in children under 2 years of age.
- Caution should be taken in patients suffering from or with a history of peptic ulcer.
- Patients suffering from bronchial asthma must be strictly controlled during the therapy; should bronchospasm occur, the treatment must immediately be suspended.
- Stenac Granules contains dextrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Stenac Granules. Patients with rare hereditary problems of glucose-galactose malabsorption should not take this medicine.
- Stenac Granules contains colouring agent E110: it may cause allergic reactions.
- The possible presence of a sulphureous odour does not indicate an alteration of the product but is a characteristic of the active ingredient contained in this preparation.
- (p) When should you consult your doctor?
- ✓ If you notice any side effects that you think are caused by the medicine.
 - ✓ Any information you want to know more about the medicine.
- (q) Use during pregnancy and lactation
- If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.
- (r) Effects on ability to drive and use machines
- Acetylcysteine has no known influence on the ability to drive and use machines.