

PROFESSIONAL INFORMATIONScheduling status: S0

D34.1 Amino Acids. Complementary Medicine: Health Supplement.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety and intended use.

1. NAME OF THE MEDICINE**GNC L-LYSINE TABLETS 1000 mg****2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains:

L-lysine (as L-lysine monohydrochloride)	1000 mg
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Contains sugar (200 mg lactose monohydrate per tablet)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

White, capsule-shaped tablet.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

L-lysine is an essential amino acid, necessary for the maintenance of good health and involved in muscle protein synthesis. L-Lysine supports the repair and maintenance of tissue. It is involved in the production of collagen.

4.2 Posology and method of administrationPosology*Adults 18 years and older:*

Take one (1) tablet up to three times a day, an hour before meals or on an empty stomach. Do not exceed the recommended daily dosage.

Method of administration

This medicine is taken orally. The tablet should be swallowed with water.

4.3 Contraindications

- Known hypersensitivity to any of the ingredients.
- Patients with hyperlysinaemia or hyperlysinuria.
- Lysinuric protein intolerance.

4.4 Special warnings and precautions for use

Take care

- in patients with renal or hepatic disease before commencing with L-Lysine supplementation.
- when using L-lysine together with high doses of calcium supplements.
- in patients with gall bladder disease. High doses of L-lysine may increase the risk of gallstone formation.
- Not suitable for children under the age of 18 years unless under the direct supervision of a relevant health care provider.
- L-LYSINE TABLETS contain lactose. Patients with the rare hereditary conditions of lactose / fructose or galactose intolerance should not take L-LYSINE TABLETS.

4.5 Interaction with other medicines and other forms of interaction

Patients with chronic conditions or those taking any chronic medication should consult a medical practitioner before taking L-LYSINE TABLETS. Not all possible interactions with other medications may be included in this leaflet.

The use of L-LYSINE TABLETS with calcium supplements should be monitored as L-LYSINE TABLETS may increase the intestinal absorption and reduce the renal elimination of calcium and raise calcium concentrations. Care should be taken in patients with heart disease or those in hypercalcaemic states.

4.6 Fertility, pregnancy and lactation

The safety of L-LYSINE TABLETS in fertility, pregnancy and lactation has not yet been established. Patients that are pregnant or breastfeeding should consult with a health care professional before supplementation with L-lysine.

4.7 Effects on ability to drive and use machines

L-LYSINE TABLETS are not expected to have an influence on the ability to drive and use machines. It is not always possible to predict to what extent it may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which L-LYSINE TABLETS affects them.

4.8 Undesirable effects

Tabulated summary of adverse reactions:

System Organ Class	
Gastrointestinal disorders	
<i>Less frequent</i>	Diarrhoea, nausea and stomach pain
Immune system disorders	
<i>Frequency unknown:</i>	Hypersensitivity reaction

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

In overdose, side effects as indicated in Section 4.8, can be precipitated and/or be of increased severity. Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

L-Lysine is the bioactive form of lysine, an essential amino acid in human nutrition. Essential amino acids cannot be produced by the body and therefore need to be obtained through diet or supplementation. L-Lysine plays a major role in protein synthesis and is essential for growth, repair and maintenance of tissues in the body. It is important for the formation of collagen and elastin. L-Lysine may increase the absorption of calcium in the body and may also reduce its excretion.

5.2 Pharmacokinetic properties

Absorption of lysine starts from the lumen of the small intestine into enterocytes through an active sodium dependent transport mechanism. After absorption it is used by the enterocytes themselves in their functions and the rest is sent to the bloodstream and the hepatic portal circulation. It is partially metabolised in the liver. Unmetabolised lysine is rapidly transported to other tissues where it is used for cellular functions or metabolised. High concentrations of lysine can be reached in muscle tissue 5 to 7 hours after ingestion.

5.3 Preclinical safety data

There are no other known preclinical safety data of relevance to the prescriber which are additional to that already included in other sections.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide and sodium starch glycollate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25°C, in a dry place in the original container

6.5 Nature and contents of container

HDPE container with a HDPE flip top lid, a foam insert and a silica gel desiccant. The container is sealed with a heat induction seal. Pack sizes of 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

GNC South Africa (Pty) Ltd, Central office park No.4, 257 Jean Avenue, Centurion, 0157.

8. REGISTRATION NUMBER(S)

To be allocated by SAHPRA upon registration

9. DATE OF FIRST AUTHORISATION

To be allocated by SAHPRA upon registration.

GNCLYS/PI-01/AUG24