

NATURAL HEALTH PRODUCT

LYSINE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

December 18, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)
		Common name(s)
<ul style="list-style-type: none"> ▶ (S)-2,6-Diaminohexanoic acid ▶ L-Lysine 	<ul style="list-style-type: none"> ▶ L-Lysine ▶ Lysine 	<ul style="list-style-type: none"> ▶ L-Lysine ▶ L-Lysine monohydrochloride ▶ L-Lysine acetate ▶ L-Lysine dihydrochloride

References: Proper names: O'Neil et al. 2001; Common names: O'Neil et al. 2001; Source materials: O'Neil et al. 2001, USP 30 2007.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



Use(s) or Purpose(s)

- ▶ Source of/(an) essential amino acid for the maintenance of good health (Sweetman 2007; IOM 2002).
- ▶ Source of/(an) essential amino acid involved in muscle protein synthesis (Sweetman 2007; IOM 2002).
- ▶ Helps to reduce the recurrence of herpes simplex virus (HSV) infection (e.g. cold sores) (Wright 1994; Griffith et al. 1987; Simon et al. 1985; McCune et al. 1984; Miller et al. 1984; Thein et al. 1984; Walsh et al. 1983; Griffith et al. 1978).
- ▶ Helps in collagen formation (Shils et al. 2006; IOM 2002; Groff and Gropper 2000).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Reduce the recurrence of HSV infection

1000 - 3000 milligrams, per day (Wright 1994; Griffith et al. 1987; Simon et al. 1985; McCune et al. 1984; Miller et al. 1984; Thein et al. 1984; Walsh et al. 1983; Griffith et al. 1978).

Other uses

133 - 3000 milligrams, per day (Wright 1994; Griffith et al. 1987; Simon et al. 1985; McCune et al. 1984; Miller et al. 1984; Thein et al. 1984; Walsh et al. 1983; Griffith et al. 1978).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)



Products providing more than 300 mg of lysine, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (Goldman and Ausiello 2004).

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Product Ingredient Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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