Lysine

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LYSINE Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 104 KB) 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) (S)-2,6-Diaminohexanoic acid L-Lysine L-Lysine 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 Products Ingredients 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. References Cited Goldman L, Ausiello D, editors. Cecil Textbook of Medicine, Volume 1, 22nd edition. 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recurrent herpes simplex infection. Archives of Dermatology 1985;121(2):167-168. Sweetman SC, editor. Martindale: The Complete Drug Reference, 35 th edition. London (UK): Pharmaceutical Press; 2007. Thein DJ, Hurt WC. Lysine as a prophylactic agent in the treatment of recurrent herpes simplex labialis. Oral Surgery, Oral Medicine and Pathology 1984;58(6):659-666. USP 30 2007: United States Pharmacopeia and the National Formulary (USP 30 - NF 25). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2007. Walsh DE, Griffith RS, Behforooz A. Subjective response to lysine in the therapy of herpes simplex. The Journal of Antimicrobial Chemotherapy 1983;12(5):489-496. Wright EF. Clinical effectiveness of lysine in treating recurrent aphthous ulcers and herpes labialis. General Dentistry 1994;42(1):40-42. References Reviewed Ahmad G, Mushtag T, Mirza MA, Ahmed Z. 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MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions No statement required.

DOSAGE FORM(S)

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.

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 Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions No statement required.

STORAGE CONDITION(S)

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.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)	
Common name(s)			
(S)-2,6-Diaminohexanoic acidL-Lysine	L-LysineLysine	L-LysineL-Lysine monohydrochlorideL-Lysin	e acetateL-Lysine