

# Alpha Lipoic Acid

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DL-ALPHA-LIPOIC ACID/R-ALPHA-LIPOIC ACID (PDF Version - 87 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 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 on the label. Date June 27, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source ingredient(s) Preparation(s) (+)-1,2-Dithiolane-3-pentanoic acid DL-alpha-Lipoic acid DL-alpha-Lipoic acid DL-Thioctic Acid DL-alpha-Lipoic acid Synthetic 1,2-Dithiolane-3-pentanoic acid, (R) (+)-alpha-Lipoic acid R-alpha-Lipoic acid R-alpha-Lipoic acid Sodium R-(+)-lipoate Synthetic References: Proper names: NIH 2023; Common names: NIH 2023; Source information: NIH 2023. 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compndial applications. Use(s) or Purpose(s) Source of (an) antioxidant(s)/Provides (an) antioxidant(s) (Borcea et al. 1999, Marangon et al.1999). Source of (an) antioxidant(s)/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Borcea et al. 1999, Marangon et al.1999). Helps to promote healthy glucose metabolism (Morcos et al. 2001, Jacob et al. 1999, Konrad et al. 1999). Note: If DL-alpha-Lipoic or R-alpha-Lipoic acid is combined with other medicinal ingredients with antioxidant properties at Class II and III, there is an option to use the claim in plural. The singular should be used when the product only contains one chemical substance as the medicinal ingredient associated with this claim. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) DL-alpha-Lipoic acid Antioxidant Not to exceed 600 milligrams of DL-alpha-Lipoic acid, per day (Morcos et al. 2001, Borcea et al. 1999, Marangon et al.1999). Glucose metabolism 600 milligrams of DL-alpha-Lipoic acid, per day (Jacob et al. 1999, Konrad et al. 1999). R-alpha-Lipoic acid Antioxidant Not to exceed 300 milligrams of R-alpha-Lipoic acid\*, per day. Glucose metabolism 300 milligrams of R-alpha-Lipoic-acid\*, per day. \*Note: The quantity of R-alpha-lipoic acid is calculated from the quantity of DL-alpha-lipoic acid (i.e. 50%). Direction(s) for use No statement required. Combination rule No permitted combinations between the two medicinal ingredients listed in this monograph. Duration(s) of use No statement required. Risk information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Jacob et al. 1999, Konrad et al. 1999, Packer et al. 1995). Products providing 42 milligrams or more DL-alpha-lipoic acid or 21 milligrams or more R-alpha-lipoic acid, per day Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience sweating, paleness, chills, headache, dizziness and/or confusion (as these may be symptoms of serious low blood sugar) (Bae et al., 2013; Gullo et al., 2014; Bresciani et al., 2011; Chang et al., 2009). 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations. 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Bae SM, Bae MN, Kim EY, Kim IK, Seo MW, Shin JK, Cho SR, Jeong GH. Recurrent Insulin Autoimmune Syndrome Caused by  $\alpha$ -Lipoic Acid in Type 2 Diabetes. *Endocrinol Metab* (Seoul). 2013;28(4):326-330. Borcea V, Nourooz-Zadeh J, Wolff SP, Klevesath M, Hofmann M, Urich H, Wahl P, Ziegler R, Tritschler H, Halliwell B, Nawroth PP. Alpha-Lipoic acid decreases oxidative stress even in

diabetic patients with poor glycemic control and albuminuria. *Free Radical Biology & Medicine* 1999;22(11/12):1495-1500. Bresciani E, Bussi A, Bazzigaluppi E, Balestrieri G. Insulin autoimmune syndrome induced by  $\alpha$ -lipoic acid in a Caucasian woman: case report. *Diabetes Care*. 2011 Sep;34(9):e146. doi: 10.2337/dc11-0600. Chang HJ, Choi HS, Park MY, Leem SM, Jang YS, Park KS, Lee JM. A case of insulin autoimmune syndrome related to alpha-lipoic acid. *Korean J Med* 2009;76:600-604. Gullo D, Evans JL, Sortino G, Ira D, Goldfine and Vigneri R. Insulin autoimmune syndrome (Hirata Disease) in European Caucasians taking  $\alpha$ -lipoic acid. *Clinical Endocrinology* 2014;81: 204-209. Jacob S, Ruus P, Hermann R, Tritschler HJ, Maerker E, Renn W, Augustin HJ, Dietze GJ, Rett K. Oral administration of RAC- $\alpha$ -lipoic acid modulates insulin sensitivity in patients with type-2 diabetes mellitus: a placebo-controlled pilot trial. *Free Radical Biology & Medicine* 1999;27(3-4):309-314. Khanna S, Atalay M, Laaksonen DE, Gul M, Roy S, Sen CK. Alpha-lipoic acid supplementation: tissue glutathione homeostasis at rest and after exercise. *Journal of Applied Physiology* 1999;86(4):1191-1196. Konrad T, Vicini P, Kusterer K, Höflich A, Assadkhani A, Böhles HJ, Sewell A, Tritschler HJ, Cobelli C, Usadel KH. Alpha-Lipoic acid treatment decreases serum lactate and pyruvate concentrations and improves glucose effectiveness in lean and obese patients with type 2 diabetes. *Diabetes Care* 1999;22(2):280-287. Marangon K, Devaraj S, Tirosh O, Packer L, Jialal I. Comparison of the effect of alpha-lipoic acid and alpha-tocopherol supplementation on measures of oxidative stress. *Free Radical Biology & Medicine* 1999;27(9/10):1114-1121. Morcos M, Borcea V, Isermann B, Gehrke S, Ehret T, Henkels M, Schiekofer S, Hofmann M, Amiral J, Tritschler H, Ziegler R, Wahl P, Nawroth PP. Effect of  $\alpha$ -lipoic acid on the progression of endothelial cell damage and albuminuria in patients with diabetes mellitus: an exploratory study. *Diabetes Research and Clinical Practice* 2001;52(3):175-183. NIH 2023: National Institutes of Health. PubChem. Bethesda (MD): National Library of Medicine, US Department of Health & Human Services. [Accessed 2023 October 23]. Available from: <https://pubchem.ncbi.nlm.nih.gov/> Packer L, Witt EH, Tritschler HJ. Alpha-Lipoic acid as a biological antioxidant. *Free Radical Biology & Medicine* 1995;19(2):227-250. Reljanovic M, Reichel G, Rett K, Lobisch M, Schuette K, Möller W, Tritschler HJ, Mehnert H. Treatment of diabetic polyneuropathy with the antioxidant thioctic acid (alpha-lipoic acid): a two year multicenter randomized double-blind placebo-controlled trial (ALADIN II). *Alpha Lipoic Acid in Diabetic Neuropathy*. *Free Radical Research* 1999;31(3):171-179. Ruhnau KJ, Meissner HP, Finn JR, Reljanovic M, Lobisch M, Schütte K, Nehrdich D, Tritschler HJ, Mehnert H, Ziegler D. Effects of 3-week oral treatment with the antioxidant thioctic acid (alpha-lipoic acid) in symptomatic diabetic polyneuropathy. *Diabetic Medicine* 1999;16(12):1040-1043. Sola S, Mir MQ, Cheema FA, Khan-Merchant N, Menon RG, Parthasarathy S, Khan BV. Irbesartan and lipoic acid improves endothelial function and reduce markers of inflammation in the metabolic syndrome: results of the Irbesartan and Lipoic Acid in Endothelial Dysfunction (ISLAND) study. *Circulation* 2005;111(3):343-348. References reviewed Burekovic A, Terzic M, Alajbegovic S, Vukojevic Z, Hadzic N. The role of alpha-lipoic acid in diabetic polyneuropathy treatment. *Bosnian Journal of Basic Medical Science* 2008;8(4):341- 345. Kamenova P. Improvement of insulin sensitivity in patients with type 2 diabetes mellitus after oral administration of alpha-lipoic acid. *Hormones (Athens)* 2006;5(4):251-258. McIntyre RS, Soczynska JK, Lewis GF, MacQueen GM, Konarski JZ, Kennedy SH. Managing psychiatric disorders with antidiabetic agents: translational research and treatment opportunities. *Expert Opinion on Pharmacotherapy* 2006;7(10):1305-1321. Mignini F, Streccioni V, Tomassoni D, Traini E, Amenta F. Comparative crossover, randomized, open-label bioequivalence study on the bioequivalence of two formulations of thioctic acid in healthy volunteers. *Clinical and Experimental Hypertension* 2007;29(8):575-586. Sharman JE, Gunaruwan P, Knez WL, Schmitt M, Marsh SA, Wilson GR, Cockcroft JR, Coombes JS. Alpha-lipoic acid does not acutely affect resistance and conduit artery function or oxidative stress in healthy men. *British Journal of Clinical Pharmacology* 2004;58(3):243-248. Vincent HK, Bourguignon CM, Vincent KR, Taylor AG. Effects of alpha-lipoic acid supplementation in peripheral arterial disease: a pilot study. *Journal of Alternative and Complementary Medicine* 2007;13(5):577-584. Zembron-Lacny A, Szyszka K, Szygula Z. Effect of cysteine derivatives administration in healthy men exposed to intense resistance exercise by evaluation of pro-antioxidant ratio. *Journal of Physiological Science* 2007;57(6):343-348. Ziegler D, Ametov A, Barinov A, Dyck PJ, Gurieva I, Low PA, Munzel U, Yakhno N, Raz I, Novosadova M, Maus J, Samigullin R. Oral treatment with alpha-lipoic acid improves symptomatic diabetic polyneuropathy: the SYDNEY 2 trial. *Diabetes Care* 2006;29(11):2365-2370. Report a problem on this page  
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## DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

## RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Jacob et al. 1999, Konrad et al. 1999, Packer et al. 1995). Products providing 42 milligrams or more DL-alpha-lipoic acid or 21 milligrams or more R-alpha-lipoic acid, per day Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience sweating, paleness, chills, headache, dizziness and/or confusion (as these may be symptoms of serious low blood sugar) (Bae et al., 2013; Gullo et al., 2014; Bresciani et al., 2011; Chang et al., 2009). 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 CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

## 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.

Proper name(s)	Common name(s)	Source information	
Source ingredient(s)	Preparation(s)		
(+)-1,2-Dithiolane-3-pentanoic acidDL-alpha-Lipoic acid	DL-alpha-Lipoic acidDL-Thioctic Acid	DL-alpha-Lipoic acid	Synthetic
1,2-Dithiolane-3-pentanoic acid, (R)	(+)-alpha-Lipoic acidR-alpha-Lipoic acid	R-alpha-Lipoic acidSodium R-(+)-lipoate	Synthetic