

NATURAL HEALTH PRODUCT

DL-ALPHA-LIPOIC ACID/R-ALPHA-LIPOIC ACID

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 January 26, 2024

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)
<ul style="list-style-type: none"> • (+-)-1,2-Dithiolane-3-pentanoic acid • DL-alpha-Lipoic acid 	<ul style="list-style-type: none"> • DL-alpha-Lipoic acid • DL-Thioctic Acid 	DL-alpha-Lipoic acid	Synthetic
1,2-Dithiolane-3-pentanoic acid, (R)	<ul style="list-style-type: none"> • (+)-alpha-Lipoic acid • R-alpha-Lipoic acid 	<ul style="list-style-type: none"> • 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 Compendial 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, there is an option to use the claim in plural. The singular should be used when the product only contains one chemical substance (e.g. DL-alpha-Lipoic acid) as the medicinal ingredient associated with the 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.

Product Facts	
Medicinal ingredient in each capsule	
DL-alpha-Lipoic acid	XX mg
OR	
R-alpha-Lipoic acid	
Uses	
<ul style="list-style-type: none"> • Source of an antioxidant/Provides an antioxidant • Source of an antioxidant/Provides an antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals • Helps to promote healthy glucose metabolism 	
Warnings	
If applicable:	
Allergens: food allergen, gluten (gluten source), sulphites	
Contains aspartame	
Ask a health care practitioner before use if:	
<ul style="list-style-type: none"> • you are pregnant or breastfeeding. • you have diabetes. 	
<i>Products providing 42 milligrams or more of DL-alpha-lipoic acid or 21 milligrams or more of R-alpha-lipoic acid, per day</i>	
Stop use and ask a health care practitioner if you experience sweating, paleness, chills, headache, dizziness and/or confusion (as these may be symptoms of serious low blood sugar).	
Directions	
Adults 18 years and older: Take X capsule(s), X times a day.	
Other information	
(Add any other storage information)	

Non-medicinal ingredients

List all NMIs

Questions? Call 1-XXX-XXX-XXXX

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