

## NATURAL HEALTH PRODUCT

### DL-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

June 3, 2019

#### 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 ingredient(s)	
		Common name(s)	Preparation(s)
<ul style="list-style-type: none"> <li>▶ (+-)-1,2-Dithiolane-3-pentanoic acid</li> <li>▶ DL-alpha-Lipoic acid</li> </ul>	<ul style="list-style-type: none"> <li>▶ DL-alpha-Lipoic acid</li> <li>▶ DL-Thioctic Acid</li> </ul>	DL-alpha-Lipoic acid	Synthetic

References: Proper names: NIH 2016; Common names: NIH 2016; Source ingredient: NIH 2016.

#### 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/Provides antioxidants (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).

### **Dose(s)**

#### **Subpopulation(s)**

Adults 18 years and older

#### **Quantity(ies)**

##### *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).

#### **Direction(s) for use**

No statement required.

#### **Duration(s) of use**

No statement required.

### **Risk information**

#### **Caution(s) and warning(s)**

##### *All products*

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant, breastfeeding or have diabetes (Jacob et al. 1999, Konrad et al. 1999, Packer et al. 1995).



*Products providing 42 milligrams or more of DL-alpha lipoic acid, per day*

Stop use and consult 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**

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**

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