

## NATURAL HEALTH PRODUCT

### L-THEANINE

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)	Source material(s)		Preparation(s)
		Common name(s)	Proper name(s)	Part(s)	
<ul style="list-style-type: none"> <li>▶ L-Theanine</li> <li>▶ N-Ethyl-L-glutamine</li> </ul>	L-Theanine	N/A	<i>Camellia sinensis</i>	Leaf	Isolate
		L-Theanine	N/A	N/A	Synthetic

References: Proper names: NIH 2015, O'Neil et al. 2013; Common name: NIH 2015; Source materials: O'Neil et al. 2013, Zajac et al. 2003, Gennaro 2000 .

#### 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)**

Helps to temporarily promote relaxation (Nobre et al. 2008; Kimura et al. 2007; Lu et al. 2004).

### **Dose(s)**

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

Adults 18 years and older

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

200 - 250 milligrams of L-Theanine, per day (Kimura et al. 2007; Lu et al. 2004; Song et al. 2002; Kobayashi et al. 1998).

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

No statement required.

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

No statement required.

### **Risk information**

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

No statement required.

#### **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.
- ▶ The assay must demonstrate that the percentage purity of the medicinal ingredient is no less than 98% L-theanine.
- ▶ The Finished Products Specifications must include testing for chemical identity and assay/purity of the medicinal ingredient L-theanine at the raw material or finished product stage using an appropriate enantiomerically selective separation method (i.e. HPLC/APCI-MS, RP-HPLC, etc.).
- ▶ If testing is conducted at the raw material stage, data to demonstrate that the ingredient does not undergo racemization must be provided.

## References cited

Kimura K, Ozeki M, Juneja LR, Ohira H. 2007. L-Theanine reduces psychological and physiological stress responses. *Biological Psychology* 74(1):39-45.

Kobayashi K, Nagato Y, Aoi N, Juneja LR, Kim M, Yamamoto T, Sugimoto S. 1998. The effects of L-theanine on the release of alpha-brain waves in human volunteers. *Nippon Noeigikagaku Kaishi* 72(2):153-157.

Lu K, Gray MA, Oliver C, Liley DT, Harrison BJ, Bartholomeusz CF, Phan KL, Nathan PJ. 2004. The acute effects of L-theanine in comparison with alprazolam on anticipatory anxiety in humans. *Human Psychopharmacology* 19(7):457-65.

NIH 2015: National Institute of Health [Internet]. [Accessed 2019 May 15]. Available from: <http://chem.sis.nlm.nih.gov/chemidplus/rn/1077-28-7>

Nobre AC, Rao A, Owen GN. 2008. L-theanine, a natural constituent in tea, and its effect on mental state. *Asia Pacific Journal of Clinical Nutrition* 17(Suppl1):167-168.

O'Neil MJ, Heckelman PE, Koch CB, Roman KJ, éditeurs. *The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals*, 15th edition. Whitehouse Station (NJ): Merck & Co., Inc. 2013.

Song CH, Chung KI, Song SW, Kim KS. 2002. The Effects of L-theanine on Mental Relaxation and Fatigue Perception. *Journal of the Korean Academy of Family Medicine* 23(5):637-645.



## References reviewed

Abdou AM, Higashiguchi S, Horie K, Kim M, Hatta H, Yokogoshi H. 2006. Relaxation and immunity enhancement effects of gamma-aminobutyric acid (GABA) administration in humans. *Biofactors* 26(3):201-208.

Haskell CF, Kennedy DO, Milne AL, Wesnes KA, Scholey AB. 2008. The effects of L-theanine, caffeine and their combination on cognition and mood. *Biological Psychology* 77(2):113-122.