



NATURAL HEALTH PRODUCT L-GLUTAMINE

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 labels 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 July 31, 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)
<ul style="list-style-type: none"> ▶ (S)-2,5-Diamino-5-oxopentanoic acid ▶ L-Glutamine 	<ul style="list-style-type: none"> ▶ Glutamine ▶ L-Glutamine 	<ul style="list-style-type: none"> ▶ L-Glutamine ▶ L-Glutamine ethyl ester

References: Proper names: O’Neil et al. 2013, NIH 2007, USP 30 2007; Common names: O’Neil et al. 2013, NIH 2007, USP 30 2007; Source materials: 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.

Note

Liquids and solutions are not permitted due to lack of stability of the finished product (Fürst et al. 1997).



Use(s) or Purpose(s)

- ▶ Helps restore plasma glutamine levels depleted after periods of physical stress (e.g. prolonged exhaustive exercise) (Krzywkowski et al. 2001; Bowtell et al. 1999; Castell and Newsholme 1997).
- ▶ Helps support immune system health after periods of physical stress (Shils et al. 2006; Newsholme 2001; Griffiths 1999).
- ▶ Helps support digestive system health after periods of physical stress (Shils et al. 2006, Newsholme et al. 2003; IOM 2002).
- ▶ Helps to assist in muscle cell repair after exercise (Newsholme et al. 2003; IOM 2002).

The following combined use(s) or purpose(s) is/are also acceptable:

Helps restore plasma glutamine levels depleted after periods of physical stress (e.g. prolonged exhaustive exercise) and assist in muscle cell repair after exercise (Newsholme et al. 2003; IOM 2002; Krzywkowski et al. 2001; Bowtell et al. 1999; Castell and Newsholme 1997).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

5-9 grams of L-Glutamine, per day (Bowtell et al. 1999; Castell and Newsholme 1997)

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

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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