

NATURAL HEALTH PRODUCT

N-ACETYL-L-CYSTEINE

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">▶ L-alpha-Acetamido-beta-mercaptpropionic acid▶ N-Acetyl-L-cysteine	N-Acetyl-L-cysteine	N-Acetyl-L-cysteine	Synthetic

References: Proper names: ChemID 2012, Merck 2012; Common name: ChemID 2012; Source ingredient: NHPID 2019.

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 (Zembron-Lacny et al. 2009; Zembron-Lacney et al. 2007; Peake and Suzuki 2004; Huupponen et al. 1995).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Not to exceed 600 milligrams of N-Acetyl-L-cysteine, per day (Zembron-Lacny et al. 2009; Zembron-Lacney et al. 2007; Peake and Suzuki 2004; Huupponen et al. 1995).

Direction(s) for use

Take with meals (Quig 1998).

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, breastfeeding or have kidney stones (Fauci et al. 1998; Mårtensson et al. 1990).

Contraindication(s)

Do not use this product if you are taking antibiotics or nitroglycerin (Repchinsky 2008; Cederlund and Mårdh 1993; Parry and Neu 1977; Ardissino et al. 1997).

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.

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