

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date March 7, 2014

Proper name(s)

- ▶ N-Acetyl-L-Cysteine (ChemID 2012)
- ▶ L-alpha-Acetamido-beta-mercaptopropionic acid (Merck 2012)

Common name(s)

N-Acetyl-L-Cysteine (ChemID 2012)

Source material(s)

Synthetic

Route(s) of administration

Oral

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.



Use(s) or Purpose(s) Statement(s) to the effect 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)

Quantity(ies)

Up to 600 mg N-Acetyl-L-Cysteine, per day (Zembron-Lacny et al. 2009; Zembron-Lacney et al. 2007; Peake and Suzuki 2004; Huupponen et al. 1995).

Directions for use

Take with meals (Quig 1998).

Note

If the ingredient is contained in a protein supplement, the above directions for use is not required.

Duration of use

No statement required.

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- ▶ If you have kidney stones, consult a health care practitioner prior to use (Fauci et al. 1998; Mårtensson et al. 1990).

Contraindication(s)

- ▶ If you are taking antibiotics, do not use this product (Repchinsky 2008; Cederlund and Mårdh 1993; Parry and Neu 1977).
- ▶ If you are taking nitroglycerin, do not use this product (Ardissino et al. 1997).

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current NHPD *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 NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

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References reviewed

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Grandjean EM, Berthet P, Ruffmann R, Leuenberger P. Efficacy of oral long-term N-acetylcysteine in chronic bronchopulmonary disease: a meta-analysis of published double-blind, placebo-controlled clinical trials. *Clinical Therapeutics* 2000;22(2):209-221.

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