NATURAL HEALTH PRODUCT

N-ACETYLL-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


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).

References cited


References reviewed

