

NATURAL HEALTH PRODUCT

CHOLINE

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

July 1, 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)
<ul style="list-style-type: none"> ▶ (beta-hydroxyethyl)trimethylammonium ▶ 2-Hydroxy-N,N,N-trimethylethanaminium ▶ Choline 	Choline	<ul style="list-style-type: none"> ▶ Choline ▶ Choline bitartrate ▶ Choline chloride ▶ Choline dihydrogen citrate ▶ Choline orotate ▶ Lecithin ▶ Phosphatidylcholine

References: Proper names: O'neil et al. 2006; Common name: NIH 2009, USP 32 2009; Source ingredients: NIH 2009, USP 32 2009, IOM 2006, IOM 1998.

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 support liver function (IOM 2006; Shils et al. 2006; IOM 1998).
- ▶ A factor in the maintenance of good health (IOM 2006; Zeisel 2006).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

27.5 - 1,000 milligrams of Choline, per day (IOM 2006; Shils et al. 2006; HC 2005; IOM 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.

References cited

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