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)

		Source ingredient(s)
Proper name(s)	Common name(s)	
		Common name(s)
▶ (beta-	Choline	► Choline
hydroxyethyl)trimethylam		► Choline bitartrate
monium		Choline chloride
► 2-Hydroxy-N,N,N-		Choline dihydrogen citrate
trimethylethanaminium		► Choline orotate
► Choline		► Lecithin
		Phosphatidylcholine

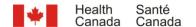
References: Proper names: O'neil et al. 2006; Common name: NIH 2009, USP 32 2009; Source ingredients: NIH 2009, USP 32 2009, IOM 2006, IOM 1998.

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

HC 2005: Health Canada 2005. Addition of Vitamins and Minerals to Foods: Health Canada's Proposed Policy and Implementation Plans [online]. Ottawa (ON): Health Canada. [Accessed 2019 May 10]. Available from:

http://publications.gc.ca/collections/Collection/H58-1-2-1999E.pdf

IOM 2006: Institute of Medicine. Otten JJ, Pitzi Hellwig J, Meyers LD, editors. 2006. Institute of Medicine Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Washington (DC): National Academies Press.

IOM 1998: Institute of Medicine. Panel on Folate, other B Vitamins, and Choline and Subcommittee on Upper Reference Levels of Nutrients, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. 1998. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B₆, Folate, Vitamin B₁₂, Pantothenic Acid, Biotin and Choline. Washington (DC): National Academy Press.

NIH 2009: National Institutes of Health. ChemIDplus advanced [online]. 2009. Choline. Bethesda (MD): Specialized Information Services, United States National Library of Medicine, National Institutes of Health, United States Department of Health & Human Services. [Accessed 2019 May 10]. Available from: http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp

O'Neil MJ, Heckelman PE, Koch CB, Roman KJ, editors. 2006. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals, 14th edition. Whitehouse Station (NJ): Merck & Co., Inc.





Shils ME, Olson JA, Shike M, Ross AC, editors. 2006. Modern Nutrition in Health and Disease, 10th edition. Philadelphia (PA): Lippincott Williams and Wilkins.

USP 32: United States Pharmacopeial Convention. 2009. United States Pharmacopeia and the National Formulary (USP 32 - NF 27). Rockville (MD): The United States Pharmacopeial Convention.

Zeisel SH. 2006. Choline: Critical Role During Fetal Development and Dietary Requirements in Adults. Annual Review of Nutrition 26:229-250.

References reviewed

BP 2007: British Pharmacopoeia Commission. 2007. British Pharmacopoeia 2008, Volume 1. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA).

Buchman AL, Ament ME, Sohel M, Dubin M, Jenden D, Roch M, Pownall H, Farley W, Awal M, Ahn C. 2001. Choline deficiency causes reversible hepatic abnormalities in patients receiving parenteral nutrition: proof of a human choline requirement: a placebo-controlled trial. Journal of Parenteral and Enteral Nutrtion 25(5):260-268.

da Costa K, Gaffney E, Fischer LM, Zeisel SH. 2005. Choline deficiency in mice and humans is associated with increased plasma homocysteine concentration after a methionine load. The American Journal of Clinical Nutrition 81(2): 440-444.

Olthof MR, Brink EJ, Katan MB, Verhoef P. 2005. Choline supplemented as phosphatidylcholine decreases fasting and postmethionine-loading plasma homocysteine concentration in healthy men. The American Journal of Clinical Nutrition 82(1):111-117.

