



THIAMINE

- Date:** August 16, 2007
- Proper name(s):** Thiamine (Sweetman 2007; O'Neil et al. 2001)
- Common name(s):** Thiamine, vitamin B₁ (Sweetman 2007; IOM 2003; O'Neil et al. 2001)
- Source material(s):**
- ▶ Thiamine/thiamine monochloride (O'Neil et al. 2001)
 - ▶ Thiamine diphosphate (O'Neil et al. 2001)
 - ▶ Thiamine hydrochloride (Sweetman 2007; IOM 2003; O'Neil et al. 2001)
 - ▶ Thiamine mononitrate (Sweetman 2007; IOM 2003; O'Neil et al. 2001)
 - ▶ Thiamine monophosphate (Sweetman 2007; O'Neil et al. 2001)

Note: The slash (/) indicates that the terms are synonyms. Either term may be selected by the applicant.

Route(s) of administration: Oral

Dosage form(s): Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewable tablets, caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable. This monograph is not intended to include food-like dosage forms such as bars, gums or beverages.

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

General: A factor in the maintenance of good health (IOM 2006; IOM 1998).

Specific:

- ▶ Helps the body to metabolize carbohydrates and proteins (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1998).
- ▶ Helps the body to metabolize fats (Shils et al. 2006; Groff and Gropper 2000; IOM 1998).
- ▶ Helps normal growth (Shils et al. 2006; Groff and Gropper 2000).

Dose-specific:

For products providing daily doses of thiamine at or above the Recommended Dietary Allowance (RDA) (adjusted for the life stage groups), the following use or purpose is acceptable: Helps to prevent thiamine deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1998).
 [Note: Thiamine deficiency is rare in North America (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1998).]

See Appendix 1 for definitions and Table 2 in Appendix 2 for RDA values.

Dose(s):

Table 1: Dose information for thiamine presented as dose per day

Life stage group		Thiamine (mg/day)	
		Minimum ¹	Maximum ²
Children	1-3 y	0.04	100
	4-8 y	0.04	100
Adolescents	9-13 y	0.04	100
	14-18 y	0.07	100
Adults ³	≥ 19 y	0.07	100

¹Based on approximately 5% of the highest RDA (IOM 2006). See Appendix 1 for definitions and Table 2 in Appendix 2 for RDA values.

²Maximum dose supported by the following references: HC 2006 and Gokhale et al. 1996.

³Includes pregnant and breastfeeding women.

Duration of use: No statement required.

Risk information: Statement(s) to the effect of:

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 NHPD *List of Acceptable Non-medicinal Ingredients* and must meet the limitations outlined in the list.

Specifications: Must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.

References:

Gokhale LB. Curative treatment of primary (spasmodic) dysmenorrhea. *Indian Journal of Medical Research* 1996;103:227-231.

Groff J, Gropper S. *Advanced Nutrition and Human Metabolism*, 3rd edition. Belmont (CA): Wadsworth/Thomson Learning; 2000.

HC 2006: Health Canada. NHPD Expert Advisory Committee Issue Analysis Summary: What is an appropriate maximum daily dose for thiamine? Ottawa (ON): Natural Health Products Directorate, Health Canada; 2006.

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

IOM 2003: Institute of Medicine. Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine. *Food Chemicals Codex*, 5th edition. Washington (DC): National Academies Press; 2003.

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. *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B₆, Folate, Vitamin B₁₂, Pantothenic Acid, Biotin and Choline*. Washington (DC): National Academies Press; 1998.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. *The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals*, 13th edition. Whitehouse Station (NJ): Merck & Co., Inc.; 2001.

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

Sweetman SC, editor. *Martindale: The Complete Drug Reference*, 35th edition. London (UK): Pharmaceutical Press; 2007.

Appendix 1: Definitions

Recommended Dietary Allowances (RDA): The average daily dietary nutrient intake level sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group (IOM 2006).

Appendix 2: RDA Values

The RDA values for thiamine are provided below. For the purpose of this monograph, these values are intended to:

- ▶ provide targets for setting appropriate supplement dosage levels;
- ▶ provide the minimum dose for the use of the dose-specific use or purpose: “Helps to prevent thiamine deficiency”;
- ▶ facilitate the optional labelling of % RDA values.

Table 2: Recommended Dietary Allowance values for thiamine based on life stage group (IOM 2006)

Life stage group		Thiamine (mg/day)
Children	1-3 y	0.5
	4-8 y	0.6
Adolescent males	9-13 y	0.9
	14-18 y	1.2
Adult males	≥ 19	1.2
Adolescent females	9-13 y	0.9
	14-18 y	1.0
Adult females	≥ 19	1.1
Pregnancy	14-50 y	1.4
Breastfeeding	14-50 y	1.4