



VITAMIN D

- Date:** August 16, 2007
- Proper name(s):** Vitamin D (Sweetman 2007; IOM 2003; O’Neil et al. 2001)
- Common name(s):** Vitamin D, vitamin D₂, vitamin D₃ (Sweetman 2007; IOM 2003; O’Neil et al. 2001)
- Source material(s):**
- ▶ Vitamin D₂/Ergocalciferol (Sweetman 2007; IOM 2003 O’Neil et al. 2001)
 - ▶ Vitamin D₃/Cholecalciferol (Sweetman 2007; IOM 2003; 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 1997).

Specific:

- ▶ For all products:
 - ▶ Helps in the development and maintenance of bones (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1997).

- ▶ Helps in the development and maintenance of teeth (Shils et al. 2006).
- ▶ Helps in the absorption and use of calcium and phosphorus (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1997).
- ▶ For products providing calcium as a medicinal ingredient, if the following statement is used it must be verbatim:
“Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis” (Shils et al. 2006; Groff and Gropper 2000; NIH 2000).

Dose-specific: For products providing daily doses of vitamin D at or above the Adequate Intake (AI) (adjusted for the life stage groups), the following use or purpose is acceptable:
Helps to prevent vitamin D deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1997).

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

Dose(s):

Table 1: Dose information for vitamin D presented as dose per day

Life stage group		Vitamin D (µg/day)	
		Minimum ¹	Maximum ²
Infants	0-12 mo	0.2	25
Children	1-3 y	0.2	25
	4-8 y	0.2	25
Adolescents	9-13 y	0.2	25
	14-18 y	0.8	25
Adults ³	≥ 19 y	0.8	25

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

²These values are based on the *Food and Drug Regulations* Schedule F limit (HC 2007).

³Includes pregnant and breastfeeding women.

Conversion Factors:

1 IU of vitamin D activity per:
= 0.025 µg cholecalciferol (IOM 2006)
= 0.025 µg ergocalciferol

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:

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

HC 2007: Health Canada. *Food and Drug Regulations* (F-27 – C.R.C., c.870). Ottawa (ON): Health Canada; 2007. [Accessed 2007-06-05]. Available at: <http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/text.html>

IOM 2006: Institute of Medicine. Otten JJ, Pitz 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 1997: Institute of Medicine. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride*. Washington (DC): National Academies Press; 1997.

NIH 2000: National Institute of Health. *Osteoporosis Prevention, Diagnosis, and Therapy*. NIH Consensus Statement Online 2000;17(1):1-36. Bethesda (MD): National Institute of Health; March 27-29, 2000. [Accessed 2007-03-21]. Available from: <http://www.consensus.nih.gov/2000/2000Osteoporosis111html.htm>

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, 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

Adequate Intake (AI): The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate; used when a Recommended Dietary Allowance (RDA) cannot be determined (IOM 2006).

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: AI Values

The AI values for vitamin D 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 vitamin D deficiency”;
- ▶ facilitate the optional labelling of % AI values.

Table 2: Adequate Intake values based on life stage group (IOM 2006)

Life stage group		Vitamin D ($\mu\text{g}/\text{day}$)
Infants	0-12 mo	5
Children	1-3 y	5
	4-8 y	5
Adolescents	9-13 y	5
	14-18 y	5
Adults	19-50 y	5
	51-70 y	10
	>70 y	15
Pregnancy	14-50 y	5
Breastfeeding	14-50 y	5