



## VITAMIN B<sub>12</sub>

- Date:** November 8, 2007
- Proper name(s):** Vitamin B<sub>12</sub> (Sweetman 2007; IOM 2003; O'Neil et al. 2001)
- Common name(s):** Cyanocobalamin, vitamin B<sub>12</sub> (Sweetman 2007; IOM 2003; O'Neil et al. 2001)
- Source material(s):**
- ▶ Cyanocobalamin/Vitamin B<sub>12</sub> (Sweetman 2007; IOM 2003; O'Neil et al. 2001)
  - ▶ Hydroxocobalamin (Van Der Kuy et al. 2002; Chalmers et al. 2000; EC 2000; Zeitlin et al. 1985; Yamagata et al. 1966)
  - ▶ Methylcobalamin (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, chewing gums or beverages.

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

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

**Specific claims:**

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

**Dose-specific claim:**

For products providing daily doses of vitamin B<sub>12</sub> at or above the Recommended Dietary Allowance (RDA) (adjusted for the life stage groups), the following use or purpose is acceptable:  
Helps to prevent vitamin B<sub>12</sub> deficiency (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 vitamin B<sub>12</sub> presented as dose per day

Life stage group		Vitamin B <sub>12</sub> (µg/day)	
		Minimum <sup>1</sup>	Maximum <sup>2</sup>
Children	1-3 y	0.09	1,000
	4-8 y	0.09	1,000
Adolescents	9-13 y	0.09	1,000
	14-18 y	0.14	1,000
Adults <sup>3</sup>	≥ 19 y	0.14	1,000

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

<sup>2</sup> Maximum dose supported by the following references: HC 2006 and FSA 2003.

<sup>3</sup> Includes 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:**

Chalmers RA, Bain MD, Costello I. Oral cobalamin therapy. *Lancet* 2000;355(9198):148.

EC 2000: European Commission. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake level of Vitamin B<sub>12</sub>. Brussels (BE): European Commission, SCF/CS/NUT/UPPLEV/42 Final 28 November 2000. [Accessed 2007-09-26]. Available from: [http://ec.europa.eu/food/fs/sc/scf/out80\\_en.html](http://ec.europa.eu/food/fs/sc/scf/out80_en.html).

FSA 2003: Food Standards Agency. Expert Group on Vitamins and Minerals. Risk Assessment: Vitamin B<sub>12</sub>. London (UK): Food Standards Agency, Expert Group on Vitamins and Minerals 2003. [Accessed 2007-06-04] Available at: [www.food.gov.uk/multimedia/pdfs/evm\\_b12.pdf](http://www.food.gov.uk/multimedia/pdfs/evm_b12.pdf)

Groff J, Gropper S. *Advanced Nutrition and Human Metabolism*, 3<sup>rd</sup> 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 vitamin B<sub>12</sub>? Ottawa (ON): Natural Health Products Directorate, Health Canada; 2006.

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 Academy Press; 2006.

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

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

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

Van Der Kuy PH, Merkus FW, Lohman JJ, Ter Berg JW, Hooymans PM. Hydroxocobalamin, a nitric oxide scavenger, in the prophylaxis of migraine: an open, pilot study. Cephalalgia 2002;22(7):513-519.

Yamagata S, Goto Y, Mita M, Kikuchi J, Yamauchi Y. Treatment of diabetic neuropathy with the oral administration of hydroxocobalamin. Vitamins 1966;34(3):349-356.

Zeitlin HC, Sheppard K, Baum JD, Bolton FG, Hall CA. Homozygous transcobalamin II deficiency maintained on oral hydroxocobalamin. Blood 1985;66(5):1022-1027.

## 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 vitamin B<sub>12</sub> 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 B<sub>12</sub> deficiency”;
- ▶ facilitate the optional labelling of % RDA values.

Table 2: Recommended Dietary Allowance values for vitamin B<sub>12</sub> based on life stage group (IOM 2006)

Life stage group		Vitamin B <sub>12</sub> (µg/day)
Children	1-3 y	0.9
	4-8 y	1.2
Adolescents	9-13 y	1.8
	14-18 y	2.4
Adults	≥ 19 y	2.4
Pregnancy	14-50 y	2.6
Breastfeeding	14-50 y	2.8