

BETA-CAROTENE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

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 are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.
- Consult Appendix 1 for definitions of the following terms: Adequate Intake (AI), Recommended Dietary Allowance (RDA), Tolerable Upper Intake Level (UL).

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Proper name(s):

- ▶ (*all-E*)-1,1'-(3,7,12,16-Tetramethyl-1,3,5,7,9,11,13,15,17-octadecanonaene-1,18-diyl)bis(2,6,6-trimethylcyclohexene) (USP 32)
- ▶ *all-trans*-beta-Carotene/ *all-trans*- β -Carotene (USP 32; Sweetman 2007; IOM 2003)

Common name(s):

- ▶ *all-trans* beta-carotene/ *all-trans*- β -Carotene (USP 32; Sweetman 2007; IOM 2003)
- ▶ Beta-carotene (O'Neil et al. 2009; Sweetman 2007; IOM 2003)

Source material(s): *all-trans* beta-carotene/beta-carotene (Sweetman 2007; IOM 2003)

Route(s) of administration: Oral

Dosage form(s):

The acceptable pharmaceutical dosage forms for oral administration include, but are not limited to, chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons. This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

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

General:

- ▶ Source of vitamin A for the maintenance of good health (IOM 2006).
- ▶ Provitamin A (IOM 2006) for the maintenance of good health.

Specific:

- ▶ Source of vitamin A to help maintain eyesight, skin, membranes and immune function (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- ▶ Provitamin A (IOM 2006) to help maintain eyesight, skin membranes and immune function (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- ▶ Source of vitamin A to help in the development and maintenance of night vision (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- ▶ Provitamin A (IOM 2006) to help in the development and maintenance of night vision (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- ▶ Source of vitamin A to help in the development and maintenance of bones (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- ▶ Provitamin A (IOM 2006) to help in the development and maintenance of bones (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- ▶ Source of vitamin A to help in the development and maintenance of teeth (Shils et al. 2006).
- ▶ Provitamin A (IOM 2006) to help in the development and maintenance of teeth (Shils et al. 2006).

Dose specific: Helps to prevent vitamin A deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).

Dose(s):

Note:

- Quantity of beta-carotene must always be expressed in microgram (μg) or milligram (mg) beta-carotene.
- International Units (IU) may be provided as optional additional information on the PLA form in the “potency” field and on product labels. The following USP conversion factor is to be used:

1 IU of beta-carotene = 0.6 μg of *all-trans* beta-carotene.

For all uses or purposes except Vitamin A deficiency:

Table 1: Dose information for beta-carotene presented as µg beta-carotene per day

Life stage group		beta-carotene (µg /day) ¹	
		Minimum ²	Maximum ³
Infants	0-12 mo	180	3,600
Children	1-3 y	180	3,600
	4-8 y	180	5,400
Adolescents	9-13 y	180	10,200
	14-18 y	390	16,800
Adults ⁴	≥ 19 y	390	18,000

¹ These values were derived from the conversion factor of 6 µg of beta-carotene = 1 µg all-*trans* retinol; hence, a ratio of 6:1 beta-carotene:vitamin A, on a weight to weight basis (HC 1990; FAO/WHO 1967).

² Based on approximately 5% of the highest AI or RDA for vitamin A (IOM 2006). See Appendix 1 for definitions.

³ Based on the UL for vitamin A, which applies to total vitamin A intake from food and supplements (IOM 2006).

⁴ Includes pregnant and breastfeeding women.

For Vitamin A deficiency use or purpose:

Table 2: Dose information for beta-carotene presented as µg beta-carotene per day

Life stage group		beta-carotene ¹ (µg /day)	
		Minimum ²	Maximum ³
Infants	0-6 mo	2,400*	3,600
	7-12 mo	3,000*	3,600
Children	1-3 y	1,800	3,600
	4-8 y	2,400	5,400
Adolescent males	9-13 y	3,600	10,200
	14-18 y	5,400	16,800
Adult males	≥ 19 y	5,400	18,000
Adolescent females	9-13 y	3,600	10,200
	14-18 y	4,200	16,800
Adult females	≥ 19 y	4,200	18,000
Pregnancy	14-18 y	4,250	16,800
	19-50 y	4,270	18,000
Breastfeeding	14-18 y	7,200	16,800
	19-50 y	7,800	18,000

¹ These values were derived from the conversion factor of 6 µg of beta-carotene = 1 µg all-*trans* retinol; hence, a ratio of 6:1 beta-carotene:vitamin A, on a weight to weight basis (HC 1990; FAO/WHO 1967).

² Based on RDA and AI values for vitamin A based on life stage group (IOM 2006).

³ Based on the UL for vitamin A, which applies to total vitamin A intake from food and supplements (IOM 2006).

Duration(s) of use: No statement required.

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

Caution(s) and warning(s):

For products containing > 6,000 µg beta-carotene:

Consult a health care practitioner prior to use if you are a tobacco smoker (Touvier et al. 2005; Omenn et al. 1996; ATBC 1994).

Contraindication(s): No statement required.

Known adverse reaction(s): No statement required.

Non-medicinal ingredients: Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in that database.

Specifications:

- ▶ The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- ▶ The medicinal ingredient may comply with the specifications outlined in the Beta Carotene and Beta Carotene Capsules monographs published in the U.S. Pharmacopeia (USP 32), and the Betacarotene monographs published in the European Pharmacopoeia (Ph. Eur. 2007) and the British Pharmacopoeia (BP 2008).

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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. An AI is used when an RDA cannot be determined (IOM 2006).

Recommended Dietary Allowance (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).

Tolerable Upper Intake Level (UL): The highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase (IOM 2006).