NATURAL HEALTH PRODUCT

CARROT - *DAUCUS CAROTA* L. SSP. *SATIVUS*

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date: July 18, 2017

Proper name(s):

Daucus carota L. ssp. *sativus* (Apiaceae) (USDA 2011; McGuffin et al. 2000)

Common name(s):

Carrot (USDA 2011; McGuffin et al. 2000)

Source material(s):

Root (USDA 2012; CNF 2010)

Route(s) of administration:

Oral

Dosage form(s):

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Dosage forms by age group:

- **Children 1-2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacoia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/ suspension, powders and solution/drops (Giacoia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years:** The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

Use(s) or Purpose(s):

General

Provitamin A for the maintenance of good health (IOM 2006).

Specific

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

Note
Refer to Appendix I for a background on claims.

Dose(s):

Note
- Both the potency, expressed as the quantity of beta-carotene and the total quantity of carrot must be provided.
- 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.

All uses/purposes except vitamin A deficiency:

Table 1 Daily dose for carrot and beta-carotene

Life stage group		Beta-carotene (µg/day)[1]	Carrot (g/day)[2]
Children	1-3 y	180-3,600	0.25-5.1
	4-8 y	180-5,400	0.25-7.6
Adolescents	9-13 y	180-10,200	0.25-14.4
	14-18 y	390-16,800	0.55-23.8
Adults[3,4]	≥ 19 y	390-18,000	0.55-25.5

1. 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. Minimum doses based on approximately 5% of the highest AI or RDA for vitamin A, and the maximum doses based on the UL for vitamin A (IOM 2006). Refer to Appendix II for definitions.
3. Calculated dried carrot equivalencies for recommended beta-carotene intake using beta-carotene composition values in carrot from CNF 2010 and USDA 2012.
4. Includes pregnant and breastfeeding women.

Vitamin A deficiency:

Table 2 Daily doses for carrot and beta-carotene for vitamin A deficiency

Life stage group		Beta-carotene (µg/day)[1]	Carrot (g/day)[2]
Children	1-3 y	1,800-3,600	2.5-5.1
	4-8 y	2,400-5,400	3.4-7.6
Adolescents males	9-13 y	3,600-10,200	5.1-14.4
	14-18 y	5,400-16,800	7.6-23.8
Adult males	≥ 19 y	5,400-18,000	7.6-25.5
Adolescent females	9-13 y	3,600-10,200	5.1-14.4
	14-18 y	4,200-16,800	5.9- 23.8
Adult females	≥ 19 y	4,200-18,000	5.9-25.5
Pregnancy	14-18 y	4,500-16,800	6.4-23.8
	19-50 y	4,620-18,000	6.5-25.5
Breastfeeding	14-18 y	7,200-16,800	10.2- 23.8
	19-50 y	7,800-18,000	11.0-25.5

1. Values 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. Minimum doses based on approximately 5% of the highest AI or RDA for vitamin A, and the maximum doses based on the UL for vitamin A (IOM 2006). Refer to Appendix II for definitions.
3. Calculated dried carrot equivalencies for recommended beta-carotene intake using beta-carotene composition values in carrot from CNF 2010 and USDA 2012.

Directions for use

No statement required.

Duration of use:

No statement required.

Risk information:

Caution(s) and warning(s)

Products containing greater than 6,000 µg beta-carotene:
If you are a tobacco smoker, consult a health care practitioner prior to use (Touvier et al. 2005; Omenn et al. 1996; ATBC 1994).

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Storage conditions:

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.

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.

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Appendix I Background on Claims

Although all of the claims for beta-carotene are associated with its vitamin A activity, it is not acceptable to cite beta-carotene as a source of vitamin A. This is because the rate of conversion of beta-carotene to vitamin A in the human body depends on numerous factors (e.g., vitamin A status, dietary factors such as vegetable consumption and fat intake, genetic factors, etc.). In other words, the consumption of supplemental beta-carotene does not always result in a consistent rate of conversion to vitamin A. Nevertheless, products providing beta-carotene do contribute to vitamin A requirements and therefore, all of the health claims associated with beta-carotene are linked to its vitamin A activity.

Appendix II 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).