Health Canada Santé Canada

NATURAL HEALTH PRODUCT

CARROT – *DAUCUS CAROTA* SUBSP. *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 statements are synonymous. Either term or statement may be selected by the applicant.

Date August 5, 2019

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
Daucus carota subsp. *sativus*	Carrot	*Daucus carota* subsp. *sativus*	Root	Dried

References: Proper name: USDA 2019a, McGuffin et al. 2000; Common name: USDA 2019a, McGuffin et al. 2000; Source material: USDA 2019b, CNF 2015.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms by age group:

Children 1-2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoia et al. 2008; EMA/CHMP 2006).
Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/ suspension, powders and solution/liquid preparations (Giacoia et al. 2008; EMA/CHMP 2006).

Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

General

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

Specific

- Helps to prevent vitamin A deficiency[1] (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- Provitamin A/Source of vitamin A to help/helps in the development and maintenance of bones (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- Provitamin A/Source of vitamin A to help/helps in the development and maintenance of night vision (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- Provitamin A/Source of vitamin A to help/helps in the development and maintenance of teeth (Shils et al. 2006).
- Provitamin A/Source of vitamin A to help/helps maintain eyesight, skin, membranes and immune function (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).

The following combined use(s) or purpose(s) is/are also acceptable:

- Provitamin A/Source of vitamin A to help/helps in the development and maintenance of bones and teeth (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- Provitamin A/Source of vitamin A to help/helps in the development and maintenance of night vision, bones and teeth (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- Provitamin A/Source of vitamin A to help/helps maintain eyesight, skin, membranes and immune function and helps in the development and maintenance of night vision, bones and teeth (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- Provitamin A/Source of vitamin A for the maintenance of good health and to prevent vitamin A deficiency[1] (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).

Note
[1]Vitamin A deficiency claim: Refer to Table 3 for the dose requirements.

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Methods of preparation: Standardized extracts

All uses/purposes except vitamin A deficiency

Table 2. Dose information of Beta-carotene (micrograms) presented as dose per day, based on subpopulations

Subpopulation(s)		Beta-carotene (µg/day)[1,2]	
		Minimum	Maximum
Children	1-3 years	180	3,600
	4-8 years	180	5,400
Adolescents	9-13 years	180	10,200
	14-18 years	390	16,800
Adults[3]	19 years and older	390	18,000

[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).
[3]Includes pregnant and breastfeeding women.

Vitamin A deficiency

Table 3. Dose information of Beta-carotene (micrograms) presented as dose per day for Vitamin A deficiency claim, based on subpopulations

Subpopulation(s)		Beta-carotene (µg/day) [1]	
		Minimum	Maximum
Children	1-3 years	1,800	3,600
	4-8 years	2,400	5,400
Adolescent males	9-13	3,600	10,200
	14-18 years	5,400	16,800
Adult males	19 years and older	5,400	18,000
Adolescent females	9-13 years	3,600	10,200
	14-18 years	4,200	16,800
Adult females	19 years and older	4,200	18,000
Pregnancy	14-18 years	4,500	16,800
	19-50 years	4,620	18,000
Breastfeeding	14-18 years	7,200	16,800
	19-50 years	7,800	18,000

[1]These values are based on the RDA and AI values for vitamin A based on subpopulations (IOM 2006) and 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).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Products providing more than 6,000 µg of Beta-carotene, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician 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 Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

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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