Carrot - Daucus carota L. ssp sativus

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CARROT - DAUCUS CAROTA SUBSP. SATIVUS Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 131 KB) 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 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 years 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. References Cited ATBC (Alpha-tocopherol, beta-carotene cancer prevention) study group. The effect of vitamin E and beta carotene on the incidence of lung cancer and other cancers in male smokers. The New England Journal of Medicine1994;330(15):1029-1035. EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. 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double-tracer study design. American Journal of Clinical Nutrition 2002;75(5):900-907. Hickenbottom SJ, Lemke SL, Dueker SR, Lin Y, Follett JR, Carkeet C, Buchholz BA, Vogel JS, Clifford AJ. Dual isotope test for assessing β-carotene cleavage to vitamin A in humans. European Journal of Nutrition 2002;41(4):141-147. Institute of Medicine. Panel on Micronutrients, Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. Washington (DC): National Academy Press; 2001. 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. Lemke SL, Dueker SR, Follett JR, Lin Y, Carkeet C, Buchholz BA, Vogel JS, Clifford AJ. Absorption and retinol equivalence of β-carotene in humans is influenced by dietary vitamin A intake. Journal of Lipid Research 2003;44(8):1591-1600. Lin Y, Dueker SR, Burri BJ, Neidlinger TR, Clifford AJ. Variability of the conversion of β- carotene to vitamin A in women measured by using a double-tracer study design. American Journal of Clinical Nutrition 2000;71(6):1545-1554. Natural Health Products Regulations [Internet]. Ottawa (ON): Department of Justice Canada. [Accessed 2012 April 26]. Available from: http://laws.justice.gc.ca/en/ShowFullDoc/cr/SOR- 2003-196///en Ribaya-Mercado JD, Solon FS, Solon MA, Cabal-Barza MA, Perfecto CS, Tang G, Solon JAA, Fjeld CR, Russell RM. Bioconversion of plant carotenoids to vitamin A in Filipino school-aged children varies inversely with vitamin A status. American Journal of Clinical Nutrition 2000;72(2):455-465. Russell RM, Ross AC, Trumbo PR, West KP. Retinol equivalency ratio of β-carotene. Journal of Nutrition 2003;133(9):2915-2916. Tang G, Qin J, Dolnikowski GG, Russell RM. Vitamin A equivalence of β-carotene in a woman as determined by a stable isotope reference method. European Journal of Nutrition 2000;39(1):7- 11. Tang G, Qin J, Dolnikowski GG, Russell RM. Short-term (intestinal) and long-term (postintestinal) conversion of β-carotene to retinol in adults as assessed by a stable-isotope reference method. American Journal of Clinical Nutrition 2003;78(2):259-266. van Lieshout M, de Pee S. Vitamin A equivalency estimates: understanding apparent differences. American Journal of Clinical Nutrition 2005;81(4):943-945. van Lieshout M, West CE, Muhilal, Permaesih D, Wang Y, Xu X, van Breemen RB, Creemers AFL, Verhoeven MA, Lugtenburg J. Bioefficacy of β-carotene dissolved in oil studied in children in Indonesia. American Journal of Clinical Nutrition 2001;73(5):949-958. Van Loo-Bouwman CA, West CE, van Breeman RB, Zhu D, Siebelink E, Versloot P, Hulshof PJM, van Lieshout M, Russel FGM, Schaafsma G, Naber THJ. Vitamin A equivalency of β- carotene in healthy adults: limitations of the extrinsic dual-isotope dilution technique to measure matrix effect. British Journal of Nutrition 2009;101(12):1837-1845. Wang Z, Yin S, Zhao X, Russell RM, Tang G. β-Carotene - vitamin A equivalence in Chinese adults assessed by an isotope dilution technique. British Journal of Nutrition 2004;91(1):121- 131. West CE, Eilander A, van Lieshout M. Consequences of revised estimates of carotenoid bioefficacy for dietary control of vitamin A deficiency in developing countries. Journal of Nutrition 2002;132(9S):2920S-2926S. West CE, Eilander A, van Lieshout M. Reply to Russel et al. Journal of Nutrition 2003; 133(9):2917. World Health Organization / Food and Agricultural Organization of the United Nations. 2004. Vitamin and mineral requirements in human nutrition, 2nd edition. [online]. [Accessed 2012 April 26]. Available from: http://www.who.int/nutrition/publications/micronutrients/9241546123/en/ Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

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.

DOSE(S)

3Includes 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 subpopulationsSubpopulation(s)Beta-carotene (µg/day)1MinimumMaximumChildren1-3 years1,8003,6004-8 years2,4005,400Adolescent males9-13 years3,60010,20014-18 years5,40016,800Adult males19 years and older5,40018,000Adolescent females9-13 years3,60010,20014-18 years4,20016,800Adult females19 years and older4,20018,000Pregnancy14-18 years4,50016,80019-50 years4,62018,000Breastfeeding14-18 years7,20016,80019-50 years7,80018,000 1These 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.

STORAGE CONDITION(S)

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.

REFERENCES

Route of Administration Oral

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

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	
Adults3	19 years and older	390	18,000

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 years	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	