

Caraway

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Caraway - Carum Carvi (PDF Version - 96 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 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 on the label. Date January 31, 2025 Proper name(s), Common name(s), Source information Caraway dried seed Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Carum carvi Caraway Carum carvi Seed Dry References: Proper name: USDA 2024; Common name: Gardner and McGuffin 2013; Wiersema and Léon 1999; Source information: Bradley 2006; Blumenthal 1998. Caraway essential oil Table 2. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Carum carvi Caraway essential oil Carum carvi Seed References: Proper name: USDA 2024; Source information: Bradley 2006; Blumenthal 1998. 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: Infants 6-12 months, and Children 1-2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giaccoia 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 (Giaccoia 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 oral use are indicated in the dosage drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine (as a stomachic) to aid digestion and to help stimulate appetite (Bradley 2006; Wichtl 2004; Hoffmann 2003; Ellingwood 1983; Felter and Lloyd 1983a; Grieve 1971). (Traditionally) used in Herbal Medicine (as an antispasmodic) to help relieve digestive spasms and indigestion (Bradley 2006; ESCOP 2003; Hoffmann 2003; Blumenthal 1998; Felter and Lloyd 1983a,b; Grieve 1971). (Traditionally) used in Herbal Medicine (as a carminative) to help relieve flatulent dyspepsia (Bradley 2006; ESCOP 2003; Hoffmann 2003; Blumenthal 1998; Felter and Lloyd 1983a,b; Grieve 1971). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to aid digestion and to help stimulate appetite and to help relieve digestive spasms and indigestion). For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Caraway is traditionally used in Herbal Medicine to aid digestion and to help stimulate appetite). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) As specified below. Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Table 3. Dose information for caraway dried seed presented as dose (grams) per day Subpopulation(s) 1, 2 Caraway dried seed (g/day) Minimum Maximum Infants 6-12 months 0.06 g 1 g Children 1-3 years 0.3 g 2 g 4-9 years 0.3 g 4 g 10-11 years 0.3 g 15 g Adolescents 12-17 years 0.3 g 15 g Adults 18 years and older 0.3 g 15 g 1 The use of caraway seed in infants, children and adolescents is supported by the following references: Bradley 2006, McIntyre 2005, ESCOP 2003, Schilcher 1997. 2 Adult dose supported by the following references: Bradley 2006, Wichtl 2004, ESCOP 2003, Hoffmann 2003. *Note: Solvents allowed for the method of preparation "Non-standardized extracts (Dry extract)" as part of this monograph are ethanol and water only. Methods of preparation: Oil, Essential (water steam distillation) Table 4. Dose information for caraway essential oil presented as dose (microliters) per day Subpopulation(s) 1, 2 Caraway essential oil (µl/day) Minimum Maximum Infants 6-12 months 0.26 µl 130 µl Children 1-3 years 18 µl 260 µl 4-11 years 18 µl 390 µl Adolescents 12-17 years 18 µl 390 µl Adults 18 years

and older 18 µl 600 µl 1 The use of caraway essential oil in infants, children and adolescents is supported by the following references: Bradley 2006, McIntyre 2005, ESCOP 2003, Schilcher 1997. 2 Adult dose supported by the following references: Bradley 2006, Blumenthal 1998. Direction(s) for use No statement required. Combination rule No permitted combinations between the two medicinal ingredients listed in Tables 1 and 2. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen (ESCOP 2003). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have acute abdominal pain (ESCOP 2003). Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Brinker 2010; ESCOP 2003). 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations. 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Blumenthal M. The Complete German Commission E Monographs. Austin (TX): American Botanical Council; 1998. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (UK): British Herbal Medicine Association; 2006. Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Ellingwood F. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1919 original]. 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. Adopted September 2006. EMA/CHMP/PEG/194810/2005. [Accessed 2024 February 14]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. 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McIntyre A. Herbal Treatment of Children - Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited; 2005. Schilcher H. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (D): Medpharm Scientific Publishers; 1997. USDA 2024: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. Carum carvi L. [Accessed 2024 February 14]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3rd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers; 2004. Wiersema J, Léon B. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC; 1999. References Reviewed BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association; 1983. Moerman DE. Native American Ethnobotany. Portland (OR): Timber Press; 1998. Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (UK): C.W. Daniel Company Limited; 1988. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

Acceptable dosage forms by age group: Infants 6-12 months, and 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 (Giacchia 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 oral use are indicated in the dosage drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen (ESCOP 2003).Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have acute abdominal pain (ESCOP 2003). Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Brinker 2010; ESCOP 2003).

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 CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

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

Caraway essential oil Table 2. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Carum carvi Caraway essential oil Carum carvi Seed
References: Proper name: USDA 2024; Source information: Bradley 2006; Blumenthal 1998.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Carum carvi	Caraway	Carum carvi	Seed	Dry

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Carum carvi	Caraway essential oil	Carum carvi	Seed

Subpopulation(s)1,2	Caraway dried seed (g/day)		
Minimum	Maximum		
Infants	6-12 months	0.06 g	1 g
Children	1-3 years	0.3 g	2 g
4-9 years	0.3 g	4 g	
10-11 years	0.3 g	15 g	
Adolescents	12-17 years	0.3 g	15 g
Adults	18 years and older	0.3 g	15 g

Subpopulation(s)1,2	Caraway essential oil (µl/day)		
Minimum	Maximum		
Infants	6-12 months	0.26 µl	130 µl
Children	1-3 years	18 µl	260 µl
4-11 years	18 µl	390 µl	
Adolescents	12-17 years	18 µl	390 µl
Adults	18 years and older	18 µl	600 µl