



NATURAL HEALTH PRODUCT

CARAWAY – *CARUM CARVI*

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: July 18, 2017

Proper name(s):

Carum carvi L. (Apiaceae) (USDA 1998)

Common name(s):

- ▶ Caraway (McGuffin et al. 2000; Wiersema and León 1999)
- ▶ Carum (McGuffin et al. 2000; Wiersema and León 1999)

Essential oil:
Caraway essential oil

Source material(s):

Seed (Bradley 2006; Blumenthal 1998)

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:

- **Infants 6-12 months, and Children 1-2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacchia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacchia 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):

- ▶ Traditionally used in Herbal Medicine to aid digestion and to help stimulate appetite (stomachic) (Bradley 2006; Wichtl 2004; Hoffmann 2003; Ellingwood 1983 [1919]; Grieve 1971 [1931]; Felter and Lloyd 1983a [1898]).
- ▶ Traditionally used in Herbal Medicine to help relieve digestive spasms (anti-spasmodic) and flatulent dyspepsia (carminative) (Bradley 2006; ESCOP 2003; Hoffmann 2003; Blumenthal 1998; Felter and Lloyd 1983a [1898]; Felter and Lloyd 1983b [1898]; Grieve 1971 [1931]).

Dose(s):

Table 1: Dose information for dried caraway seed (fruit) as dose per day

Subpopulation		Dried caraway seed (fruit) (g/day)	
		Minimum	Maximum
Infants ¹	6 mo - < 1 y	0.06	1
Children ¹	1-3 y	0.3	2
Children and adolescents ¹	4-9 y	0.3	4
Adolescents and adults ²	≥ 10 y	0.3	15

¹ Supported by the following references: Bradley 2006; ESCOP 2003. The use of caraway in infants is supported by the following references: McIntyre 2005; Schilcher 1997.

² Supported by the following references: Bradley 2006; Wichtl 2004; ESCOP 2003; Hoffmann 2003

Table 2: Dose information for caraway essential oil as dose per day

Subpopulation		Caraway essential oil (µl/day)	
		Minimum	Maximum
Infants ¹	6 mo - < 1 y	0.26	130
Children ¹	1-3 y	18	260
Children and adolescents ¹	4-18 y	18	390
Adults ²	≥ 19 y	18	600

¹ Supported by the following references: Bradley 2006; ESCOP 2003. The use of caraway essential oil in infants is supported by the following references: McIntyre 2005; Schilcher 1997.

² Supported by the following references: Bradley 2006; Blumenthal 1998.

See Appendix 1 for examples of appropriate dosage preparations and frequencies, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration of use:

No statement required.

Risk information:

Caution(s) and warning(s):

- ▶ Consult a health care practitioner if symptoms persist or worsen (ESCOP 2003).
- ▶ Consult a health care practitioner prior to use if you are experiencing acute abdominal pain (ESCOP 2003).
- ▶ Consult a health care practitioner prior to use if you are pregnant or breastfeeding.

Contraindication(s):

Do not use if you are allergic to plants of the Apiaceae/Carrot family (ESCOP 2003; Brinker 2001).

Known adverse reaction(s):

Hypersensitivity (e.g., allergy) has been known to occur; in which case, discontinue use (ESCOP 2003; Brinker 2001).

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.
- ▶ The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 3 below.

Table 3: Caraway monographs published in British, European and US Pharmacopoeias



Pharmacopoeia	Monograph
British Pharmacopoeia	Caraway Fruit
European Pharmacopoeia	Caraway Fruit
US Pharmacopoeia	Caraway

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, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.

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: Next link will take you to another Web site Formulations of choice for the paediatric population. Adopted September 2006. EMA/CHMP/PEG/194810/2005. [Accessed on 2013 June 29].

ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003.

Felter HW, Lloyd JU. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983a [Reprint of 1898 original].

Felter HW, Lloyd JU. King's American Dispensatory, Volume 2, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983b [Reprint of 1898 original].

Giacoa GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. Clinical Therapeutics 2008; 30(11):2097-2101.

Grieve M. A Modern Herbal, Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication].

Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003.



McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000.

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 1998: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Carum carvi* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2008-01-23]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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.

McGuffin M, Hobbs C, Upton R, Goldberg A, editors. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press; 1997.

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.



Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use

SEED (FRUIT):

Adults \geq 19 y:

Dried seed (fruit):

- ▶ 0.5-2 g dried seed, 3 times per day (Bradley 2006)
- ▶ 1.5-6 g dried seed, per day (ESCOP 2003)

Infusion:

- ▶ 0.5-2 g dried seed, 3 times per day (Bradley 2006)
- ▶ 1.5-2 g dried seed, 1-3 times per day (Wichtl 2004)
- ▶ 1-5 g dried seed, 1-3 times per day (ESCOP 2003)
- ▶ 3.5 g dried seed, 3 times per day (Hoffmann 2003)

Directions for use: Pour 150 ml of boiling water over freshly crushed or powdered dried seeds. Infuse in a covered container for 10-15 minutes and strain (Wichtl 2004; ESCOP 2003; Hoffmann 2003).

Tincture:

- ▶ 0.1-0.8 g dried equivalent, 3 times per day (1:5, 45% alcohol, 0.5-4 ml) (Bradley 2006)
- ▶ 0.2-0.8 g dried equivalent, 3 times per day (1:5, 40% alcohol, 1-4 ml) (Hoffmann 2003)

Adolescents 10-18 y:

Dried seed (fruit): 1.5-6 g dried seed, per day (ESCOP 2003)

Infusion: 1-5 g dried seed, 1-3 times per day (ESCOP 2003)

Directions for use: Pour 150 ml of boiling water over freshly crushed or powdered dried seeds. Infuse in a covered container for 10-15 minutes and strain (ESCOP 2003).

Children and adolescents 4-9 y:

Dried seed (fruit): 1-4 g dried seed, per day (ESCOP 2003)



Children 1-3 y:

Dried seed (fruit): 1-2 g dried seed, per day (ESCOP 2003)

Infants 6 mo - < 1 y:

Dried seed (fruit): 1 g dried seed, per day (ESCOP 2003)

Infusion: 0.06 g dried seed, per day (Bradley 2006)

Directions for use: Pour 150 ml of boiling water over ½ tsp of freshly crushed or powdered dried seeds. Infuse in a covered container for 10-15 minutes and strain (Bradley 2006; Wichtl 2004). Take one teaspoonful of fresh infusion, per day.

3.6 g crushed or powdered dried seeds = 1 tsp

5 ml infusion = 1 tsp

ESSENTIAL OIL:

Adults ≥ 19 y:

- ▶ 50-200 µl caraway oil, 3 times per day (Bradley 2006)
- ▶ 6-20 µl of caraway oil (from 0.3-1 ml Concentrated Caraway Water BPC 1973), 3 times per day (Bradley 2006)
- ▶ 190-390 µl (3-6 drops) caraway oil, per day (Blumenthal 1998)

Children and adolescents 4-18 y:

190-390 µl (3-6 drops) caraway oil, per day (ESCOP 2003)

Children 1-3 y: 130-260 µl (2-4 drops) caraway oil, per day (ESCOP 2003)

Infants 6 mo - < 1 y:

- ▶ 0.26-0.38 µl of caraway oil (from 13-19 µl (2-3 drops) Concentrated Caraway Water BPC 1973), per day (Bradley 2006)
- ▶ 60-130 µl (1-2 drops) caraway oil, per day (ESCOP 2003)