

## 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

August 5, 2019

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

##### *Caraway dried seed*

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)
<i>Carum carvi</i>	Caraway	<i>Carum carvi</i>	Seed	Dried

References: Proper name: USDA 2019; Common name: McGuffin et al. 2000, Wiersema and Léon 1999; Source material: Bradley 2006, Blumenthal 1998.

##### *Caraway essential oil*

Table 2. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
<i>Carum carvi</i>	Caraway essential oil	<i>Carum carvi</i>	Seed

References: Proper name: USDA 2019; Common name: NHPID 2019; Source material: 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 this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

## 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; Felter and Lloyd 1983a; Grieve 1971).
- ▶ Traditionally used in Herbal Medicine to help relieve digestive spasms (anti-spasmodic) and indigestion/flatulent dyspepsia (carminative) (Bradley 2006; ESCOP 2003; Hoffmann 2003; Blumenthal 1998; Felter and Lloyd 1983a,b; Grieve 1971).

### Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

## Dose(s)

### Subpopulation(s)

As specified below.

### Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Table 3. Dose information for caraway dried seed presented as dose (grams) per day

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

<sup>1</sup> The use of caraway seed in infants, children and adolescents is supported by the following references: Bradley 2006, McIntyre 2005, ESCOP 2003, Schilcher 1997.

<sup>2</sup> Adult dose supported by the following references: Bradley 2006, Wichtl 2004, ESCOP 2003, Hoffmann 2003.

Methods of preparation: Oil, Essential (water steam distillation)

Table 4. Dose information for caraway essential oil presented as dose (microliters) per day

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

<sup>1</sup> 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.

<sup>2</sup> Adult dose supported by the following references: Bradley 2006, Blumenthal 1998.

### Direction(s) for use

No statement required.

### Duration(s) of use

No statement required.

### Risk information

#### Caution(s) and warning(s)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen (ESCOP 2003).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant, breastfeeding or experiencing 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**

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**

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