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

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Dried caraway seed (fruit) (g/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>Infants¹ 6 mo - &lt; 1 y</td>
<td>0.06</td>
</tr>
<tr>
<td>Children 1-3 y</td>
<td>0.3</td>
</tr>
<tr>
<td>Children and adolescents 4-9 y</td>
<td>0.3</td>
</tr>
<tr>
<td>Adolescents and adults ≥ 10 y</td>
<td>0.3</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Caraway essential oil (μl/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>Infants 6 mo - &lt; 1 y</td>
<td>0.26</td>
</tr>
<tr>
<td>Children 1-3 y</td>
<td>18</td>
</tr>
<tr>
<td>Children and adolescents 4-18 y</td>
<td>18</td>
</tr>
<tr>
<td>Adults ≥ 19 y</td>
<td>18</td>
</tr>
</tbody>
</table>

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.
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
<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Pharmacopoeia</td>
<td>Caraway Fruit</td>
</tr>
<tr>
<td>European Pharmacopoeia</td>
<td>Caraway Fruit</td>
</tr>
<tr>
<td>US Pharmacopoeia</td>
<td>Caraway</td>
</tr>
</tbody>
</table>

References cited:


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].


References reviewed:


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)