NATURAL HEALTH PRODUCT

CAYENNE – CAPSICUM ANNUUM L.

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date

September 27, 2013

Proper name(s)

Capsicum annuum L. (Solanaceae) (USDA 2010)

Common name(s)

- Cayenne (McGuffin et al. 2000)
- Chili pepper (Blumenthal et al. 2000)
- Paprika (Blumenthal et al. 2000)
- Red pepper (Blumenthal et al. 2000)

Source material(s)

Fruit (Bradley 2006; Felter and Lloyd 1983 [1898])

Route(s) of administration

- Oral
- Topical

Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
Those pharmaceutical dosage forms suited to topical administration. This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

**Use(s) or Purpose(s) Statement(s) to the effect of**

**ORAL**

- Traditionally used in Herbal Medicine to aid digestion (Bradley 2006; Ellingwood 1983 [1919]; Felter and Lloyd 1983 [1898]).
- Traditionally used in Herbal Medicine to help support peripheral circulation (Bradley 2006; Ellingwood 1983 [1919]; Wren 1907).

**TOPICAL**

- Traditionally used in Herbal Medicine (as a rubefacient/counterirritant) (Blumenthal et al. 2000; BHP 1983; Ellingwood 1983 [1919]; Felter 1983 [1922]) to help relieve the symptoms of rheumatism (Lust 1987; BPC 1934) and/or muscle and joint pain (BHP 1983; Felter and Lloyd 1983 [1898]).
- Used for the temporary relief of muscle and joint pain associated with rheumatoid arthritis or osteoarthritis, and pain of tendons and ligaments (McCarthy et al. 1992; Deal et al. 1991).
- Used to relieve cutaneous pain (Hautkappe et al. 1998) associated with conditions such as post-herpetic neuralgia (Watson et al. 1993; Bernstein et al. 1989) and diabetic neuropathy (Tandan et al. 1992; Scheffler et al. 1991; The Capsaicin Study Group 1991).

<table>
<thead>
<tr>
<th>Table 1: Recommended Conditions of Use</th>
<th>Oral</th>
<th>Topical</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong> (Adults ≥ 18 years)</td>
<td></td>
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<tr>
<td>Preparations equivalent to 15-650 mg dried fruit, per day (Bradley 2006; Blumenthal 2003; Hoffmann 2003; Lust 1987; Felter and Lloyd 1983 [1898]; Grieve 1971 [1931])</td>
<td>Preparations equivalent to 20-70 mg dried fruit, per day (BHP 1983)</td>
<td>Relief muscle, joint, tendons and ligaments pain Preparations equivalent to 0.025-0.075% capsaiacin (McCarthy et al. 1992; Deal et al. 1991) Reliecf of cutaneous pain Preparations equivalent to 0.075% capsaiacin (Watson 1993; Tandan et al. 1992; Scheffler et al. 1991; The Capsaicin Study Group 1991; Bernstein et al. 1989)</td>
</tr>
<tr>
<td><strong>Directions of Use</strong></td>
<td>No statement required.</td>
<td>Apply as needed.</td>
</tr>
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<td><strong>Duration of Use</strong></td>
<td>No statement required.</td>
<td>No statement required.</td>
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<tr>
<td><strong>Caution(s) and warning(s)</strong></td>
<td>Keep out of the reach of children.</td>
<td>For external use only.</td>
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<td></td>
<td>If symptoms persist or worsen, consult a health care practitioner.</td>
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<td></td>
<td>If you are pregnant or breastfeeding, consult a health care practitioner prior to use (Bradley 2006; Boon and Smith 2004).</td>
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<tr>
<td></td>
<td>If you have stomach ulcers or inflammation, consult a health care practitioner prior to use (Brinker 2001).</td>
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<tr>
<td><strong>Contraindication(s)</strong></td>
<td>No statement required.</td>
<td>Headache (McCleane 2000), erythema, redness, rashes and/or burning discomfort, and hypersensitivity have been known to occur (Martindale 2010; Zhang et al. 2008; APhA 2002; McCleane 2000, Hoffman 2003).</td>
</tr>
<tr>
<td><strong>Known adverse reaction(s)</strong></td>
<td>No statement required.</td>
<td></td>
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<tr>
<td></td>
<td>For external use only.</td>
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**Note**
- A claim for traditional use must include the term “Herbal Medicine”.
- Refer to Appendix 1 for examples of dosage preparations and directions for use, according to the cited references. The purpose of Appendix 1 is to provide guidance to industry.

**Non-medicinal ingredients**

Must be chosen from the current NHPD Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.
Storage conditions

Statement(s) to the effect of

No statement required.

Specifications

- The finished product specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.
- The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

References cited


Felter HW. The Eclectic Materia Medica, Pharmacology and Therapeutics. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1922 original].

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


Wren RC. Potter’s Cyclopedia of Botanical Drugs and Preparations. London (GB): Potter and Clark; 1907.

References reviewed


Johnson W. Final report on the safety assessment of Capsicum Annuum extract, Capsicum Annuum fruit extract, capsicum Annuum Resin, Capsicum Annuum fruit powder, Capsicum


Appendix 1  Examples of dosage preparations and directions for use

ORAL

Dried fruit

- 30-120 mg, 3 times per day (Bradley 2006)
- 120-145 mg, 2-3 times per day (Blumenthal 2003)
- 65-200 mg, per day (Lust 1987)
- 65-400 mg, per day (Felter and Lloyd 1983 [1898])
- 65-650 mg, per day (Grieve 1971 [1931])

Direction for use: Take with meals (Blumenthal 2003).

Infusion

- 140-280 mg dried fruit, per day (Blumenthal 2003; Hoffmann 2003; Lust 1987)
- 400 mg dried fruit, per day (Grieve 1971 [1931])

Tincture

15-50 mg dried equivalent, 3 times per day (1:20, 60% alcohol, 0.3-1 ml) (Bradley 2006)

TOPICAL

Tincture

20-70 mg dried equivalent, per day (1:3, 60% alcohol, 0.06-0.2 ml) (BHP 1983)

Directions for use: Apply as needed.

Other preparations

- 0.025% capsaicin cream (Deal et al. 1991)
- 0.075% capsaicin cream (Watson 1993; McCarthy et al. 1992; Tandan et al. 1992; Scheffler et al. 1991; The Capsaicin Study Group 1991; Bernstein et al. 1989)

Directions for use: Apply 4 times per day (Watson 1993; McCarthy et al. 1992; Tandan et al. 1992; Deal et al. 1991; Scheffler et al. 1991; The Capsaicin Study Group 1991; Bernstein et al. 1989).