GERMAN CHAMOMILE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

Note: Text in parentheses is additional optional information which can be included on the PLA and product labels at the applicants’ discretion. The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

Date: July 31, 2009

Proper name(s): Matricaria chamomilla L. (Asteraceae) Synonyms: Matricaria recutita L.; Chamomilla recutita L. Rauschert (USDA 2008)

Common name(s):

- German Chamomile (USDA 2008; McGuffin 2000)
- Chamomile (USDA 2008; McGuffin 2000)

Source material(s): Flower (Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992)

Route(s) of administration:

- Oral (ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992)
- Topical (ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992)
- Buccal (ESCOP 2003; Blumenthal et al. 2000; Bradley 1992)

Dosage form(s):

- Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable. This monograph is not intended to include foods or
food-like dosage forms such as bars, chewing gums or beverages.

- Those dosage forms suited to topical administration.
- Those dosage forms suited to buccal administration.

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

**Oral:**

- Used in Herbal Medicine to help relieve inflammatory conditions of the gastrointestinal tract (Blumenthal et al. 2000; Bradley 1992).
- (Traditionally) used in Herbal Medicine to help relieve mild digestive disturbances (such as dyspepsia, flatulence, bloating, and belching) (Mills and Bone 2005; ESCOP 2003; Bradley 1992; Felter 1922; Ellingwood 1919; Felter and Lloyd 1898).
- (Traditionally) used in Herbal Medicine as a calmative and/or sleep aid (Blumenthal et al. 2000; WHO 1999; Bradley 1992; Felter 1922; Ellingwood 1919; Felter and Lloyd 1898).

**Topical:**

Used in Herbal Medicine to help relieve minor inflammation and/or irritation of the skin (Mills and Bone 2005; ESCOP 2003; WHO 1999; Bradley 1992).

**Buccal:**

Used in Herbal Medicine to help relieve minor inflammation and/or irritation of the mucous membranes of the mouth and/or throat (ESCOP 2003; Bradley 1992; Blumenthal et al. 2000).

**Dose(s):**

**Oral:**

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children(^1)</td>
<td>2-4 y</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.0</td>
</tr>
<tr>
<td>Children and adolescents(^1)</td>
<td>5-9 y</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.0</td>
</tr>
<tr>
<td>Adolescents(^1)</td>
<td>10-14 y</td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12.0</td>
</tr>
<tr>
<td>Adolescents and adults(^1,2,3)</td>
<td>≥ 14 y</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>24.0</td>
</tr>
</tbody>
</table>

\(^1\) Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of German chamomile in children and adolescents is supported by the following references: Schilcher 1997; Bove 1996.

\(^2\) Adult dose supported by the following references: Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992.

\(^3\) Includes pregnant and breastfeeding women (ESCOP 2003; WHO 1999; Bradley 1992).

**Topical and/or Buccal:**
Subpopulation(s): Adults, adolescents, and children ≥ 2 years (Bove 2001; Schilcher 1997)

Quantity(ies):
- Preparations containing the equivalent of 3-10% dried flower (w/w or w/v) (Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992)
- Preparations containing 1% v/v fluidextract (ESCOP 2003; WHO 1999)
- Preparations containing 5% v/v tincture (ESCOP 2003; WHO 1999)
  Note: Refer to oral adult dose for acceptable quantity dried equivalent.

Directions for use:
- For topical use: Apply to affected area as needed.
- For buccal use: Rinse and/or gargle as needed.

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

Duration(s) of use: No statement required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s): Consult a healthcare practitioner if symptoms persist or worsen.

Contraindication(s): Do not use if you are allergic to plants of the Asteraceae/Compositae/Daisy family (ESCOP 2003; Brinker 2001; WHO 1999).

Known adverse reaction(s): Hypersensitivity, such as allergy, has been known to occur in which case, discontinue use (ESCOP 2003; Bradley 1992).

Non-medicinal ingredients: Must be chosen from the current NHPD Natural Health Products Ingredients Database and must meet the limitations outlined in the database.

Specifications:
- The finished product must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs. The medicinal ingredient may comply with the
specifications outlined in the pharmacopoeial monographs listed in Table 1 below.

Table 1: Monographs published in the British Pharmacopoeia (BP), European Pharmacopoeia (Ph. Eur.), and United States Pharmacopeia (USP).

<table>
<thead>
<tr>
<th>Pharmacopeia</th>
<th>Monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP</td>
<td>Matricaria Flowers</td>
</tr>
<tr>
<td>Ph. Eur.</td>
<td>Matricaria Flower</td>
</tr>
<tr>
<td></td>
<td>Matricaria Liquid Extract</td>
</tr>
<tr>
<td>USP</td>
<td>Chamomile</td>
</tr>
</tbody>
</table>

References cited:


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


References reviewed:


NHM 2006: The Natural History Museum, Linnaean Plant Typification Database [online]. 2006. Matricaria chamomilla L. London (UK): The Natural History Museum. [Accessed 2009 June 24]. Available from: http://www.nhm.ac.uk/jdsml/research-curation/research/projects/linnaeantypification/detail.dsm?ID=559000&listPageURL=list%2edsm%3fVarqtype%3dstarts%2bwith%26CVarqtype%3dstarts%2bwith%26CGenusqtype%3dstarts%2bwith%26CSpeciesqtype%3dstarts%2bwith%26Species%3drecutita%26dsort%3dGenus%252cSpecies%252cSpecies%252csort%3d%2bwith%26CSpqtype%3dstarts%2bwith%26CSpqtype%3dstarts%2bwith


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

Oral:

Dried flower:
- 6-12 g, per day (Mills and Bone 2005)
- 2-8 g, 3 times per day (WHO 1999)
- 2-4 g, 3 times per day (Bradley 1992)

Infusion:
- 6-12 g dried flower, per day (Mills and Bone 2005)
- 3 g dried flower heads (ESCOP 2003)
- 3 g dried flower, 3-4 times per day (Blumenthal et al. 2000)

Directions for use: Pour 150 ml of boiling water on dried flower heads and steep for 5-10 minutes (ESCOP 2003).

Fluidextract:
- 3 g dried equivalent, 3-4 times per day
  (1:1, 3 ml) (Blumenthal et al. 2000)
- 1-4 g dried equivalent, 3 times per day
  (1:1, 45% ethanol, 1-4 ml) (WHO 1999; Bradley 1992)

Tincture:
- 1.5-6 g dried equivalent, per day
  (1:2, 3-12 ml) (Mills and Bone 2005)
- 1.8-4 g dried equivalent, per day
  (1:5, 9-20 ml) (Mills and Bone 2005)
- 1.5-3 g dried equivalent, 3-4 times per day
  (1:2, 50% ethanol, 3-6 ml) (ESCOP 2003)
- 3 g dried equivalent, 3-4 times per day
  (1:5, 15 ml) (Blumenthal et al. 2000)
- 0.6-2 g dried equivalent, 3 times per day
  (1:5, 45% ethanol, 3-10 ml) (Bradley 1992)

Topical:

Solid or semi-solid preparations:
- 3-10% dried flower w/w or equivalent (Mills and Bone 2005; ESCOP 2003; WHO 1999; Bradley 1992)

Note: An example of acceptable preparations to be used for preparing solids or semi-solids preparations includes hydroalcoholic extracts (ESCOP 2003; WHO 1999).

Compresses, rinses, poultices:
- 3-10% m/v infusion (ESCOP 2003; Blumenthal 2000; WHO 1999)
- 1% v/v of a fluid extract (ESCOP 2003; WHO 1999)
- 5% v/v of a tincture (ESCOP 2003; WHO 1999)
- 3-10% dried flower w/v or equivalent (Mills and Bone 2005; Bradley 1992)

**Note:** Refer to oral route of administration for acceptable hydroalcoholic extract (such as fluidextract, tincture) preparations.

**Directions for use:** Apply to affected area as needed.

**Buccal:**
- 3-10% dried flower w/v or equivalent (Mills and Bone 2005; Bradley 1992)
- 3-10% w/v infusion (ESCOP 2003; Blumenthal et al. 2000; WHO 1999)
- 1% v/v of a fluid extract (ESCOP 2003; WHO 1999)
- 5% v/v of a tincture (ESCOP 2003; WHO 1999)

**Note:** Refer to oral route of administration for acceptable hydroalcoholic extract (such as fluidextract, tincture) preparations.

**Directions for use:** Rinse and/or gargle as needed.