NATURAL HEALTH PRODUCT

GERMAN CHAMOMILE – MATRICARIA CHAMOMILLA – ORAL

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.

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 18, 2017

Proper name(s):

Matricaria chamomilla L. (Asteraceae)

Synonyms: Matricaria recuita L.; Chamomilla recuita 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)

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:

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

- 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).

**Dose(s):**

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Dried flowers (g/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children</strong> 2-4 y</td>
<td></td>
<td>0.3</td>
<td>4.0</td>
</tr>
<tr>
<td>Children and adolescents 5-9 y</td>
<td></td>
<td>0.4</td>
<td>6.0</td>
</tr>
<tr>
<td>Adolescents 10-14 y</td>
<td></td>
<td>0.8</td>
<td>12.0</td>
</tr>
<tr>
<td>Adolescents and adults ≥ 15 y</td>
<td></td>
<td>1.5</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).

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:

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 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 2 below.

Table 2: Monographs published in the British Pharmacopoeia (BP), European Pharmacopoeia (Ph. Eur.), and United States Pharmacopeia (USP).

<table>
<thead>
<tr>
<th>Pharmacopoeia</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/linnaean-typification/detail.dsml?ID=559000&listPageURL=list%2edsml%3fVarqtype%3d starts%2bwith%26CVarqtype%3dstarts%2bwith%26CGenusqtype%3dstarts%2bwith%26Speciesqtype%3dstarts%2bwith%26CSpeciesqtype%3dstarts%2bwith%26Genus%2bwith%26Species%3drecutita%26sort%3dGenus%252cSpecies%26Speciesqtype%3dstarts%2bwith%26Genus%3dMatricaria%26Genusqtype%3dstarts%2bwith%26CSpqtype%3dstarts%2bwith


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

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)