NATURAL HEALTH PRODUCT

GERMAN CHAMOMILE – MATRICARIA CHAMOMILLA – BUCCAL

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 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:

Buccal (ESCOP 2003; Blumenthal et al. 2000; 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) and allow for direct contact between the affected tissue and the medicinal ingredient.

- **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) and allow for direct contact between the affected tissue and the medicinal ingredient.

- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years**: Those dosage forms suited for buccal administration which allow for direct contact between the affected tissue and the medicinal ingredient, such as gargles, rinses, and mouthwashes.

**Use(s) or Purpose(s):**

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):**

**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)

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

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 Pharmacopoeia (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:


References reviewed:


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


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.dsmI?ID=559000&listPageURL=list%2edsml%3fVarqtype%3dstarts%2bwith %26CVarqtype%3dstarts%2bwith%26CGenusqtype%3dstarts%2bwith%26CSpeciesqtype%3dstarts%2bwith%26Species%3drecutita%26sort%3dGenus%252cSpecies%26Speciesqtype%3dstarts%2bwith%26Genus%3dMatricaria%26Genusqtype%3dstarts%2bwith%26CSSpqttype%3dstarts %2bwith


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

- 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 the monograph for the oral route of administration for acceptable hydroalcoholic extract (such as fluidextract, tincture) preparations.

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