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 (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 labels at the applicants’ discretion.
► The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date October 30, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
</tr>
</thead>
</table>
| *Matricaria chamomilla* | Blue chamomile
|                     | Chamomile                                            |                    |
|                     | Common chamomile                                     |                    |
|                     | German chamomile                                     |                    |
|                     | Hungarian chamomile                                  |                    |
|                     | Matricaria                                           |                    |
|                     | Scented chamomile                                    |                    |
|                     | Scented mayweed                                      |                    |
|                     | Sweet false chamomile                                |                    |
|                     | True chamomile                                       |                    |
|                     | Wild chamomile                                       |                    |
| Matricaria chamomilla | Flower                                              | *Matricaria chamomilla* |
|                     | Dried                                                |                    |


Route of administration

Oral (ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992)
Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms by age group:

**Children 2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006).

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

**Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:** The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

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 upset (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).

The following combined use(s) or purpose(s) is/are also acceptable:

Used in Herbal Medicine to help relieve inflammatory conditions of the gastrointestinal tract and mild digestive upset (Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; Bradley 1992; Felter 1922; Ellingwood 1919; Felter and Lloyd 1898).

**Note**
Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

As specified below.
Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Table 2. Dose information of *Matricaria chamomilla* dried flower presented as dose per day

<table>
<thead>
<tr>
<th>Subpopulation(s)</th>
<th>Dried flower (grams/day)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum</td>
<td>Maximum</td>
<td></td>
</tr>
<tr>
<td><strong>Children</strong>¹</td>
<td>2-4 years</td>
<td>0.3</td>
<td>4.0</td>
</tr>
<tr>
<td></td>
<td>5-9 years</td>
<td>0.4</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>10-11 years</td>
<td>0.8</td>
<td>12.0</td>
</tr>
<tr>
<td><strong>Adolescents</strong>¹</td>
<td>12-14 years</td>
<td>0.8</td>
<td>12.0</td>
</tr>
<tr>
<td></td>
<td>15-17 years</td>
<td>1.5</td>
<td>24.0</td>
</tr>
<tr>
<td><strong>Adults</strong>²,³</td>
<td>18 years and older</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 2018). 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(s) for use**

No statement required.

**Duration(s) of use**

No statement required.

**Risk information**

**Caution(s) and warning(s)**

Consult a healthcare practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

**Contraindication(s)**

No statement required.
Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (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.

Storage conditions

No statement required.

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.

References cited


References reviewed


