



## 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 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)

**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 (Giacoaia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoaia 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 1: Dose information of *Matricaria chamomilla* dried flowers presented as dose per day

Subpopulation		Dried flowers (g/day)	
		Minimum	Maximum
Children <sup>1</sup>	2-4 y	0.3	4.0
Children and adolescents <sup>1</sup>	5-9 y	0.4	6.0
Adolescents <sup>1</sup>	10-14 y	0.8	12.0
Adolescents and adults <sup>1,2,3</sup>	≥ 15 y	1.5	24.0

<sup>1</sup> 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.

<sup>2</sup> Adult dose supported by the following references: Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992.

<sup>3</sup> 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 Pharmacopoeia (USP).

Pharmacopoeia	Monograph
BP	Matricaria Flowers
Ph. Eur.	Matricaria Flower Matricaria Liquid Extract
USP	Chamomile

**References cited:**

Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications.



Bove M. 1996. *An Encyclopedia of Natural Healing for Children and Infants*. New Canaan (CT): Keats Publishing, Incorporated.

BP 2007: British Pharmacopoeia Commission. 2007. *British Pharmacopoeia 2008, Volume 1*. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA).

Bradley PR, editor. 1992. *British Herbal Compendium, Volume 1*. Bournemouth (GB): British Herbal Medicine Association.

Brinker F. *Online Updates and Additions to Herb Contraindications and Drug Interactions*, 3<sup>rd</sup> edition. Sandy (OR): Eclectic Medical Publications; 2008. [Accessed 2009 June 24]. Available from: <http://www.eclecticherb.com/emp/updatesHCDI.html>

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EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Next link will take you to another Web site Formulations of choice for the paediatric population. Adopted September 2006. EMA/CHMP/PEG/194810/2005. [Accessed on 2013 June 29].

ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. 2003. *ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products*, 2<sup>nd</sup> edition. Exeter (GB): European Scientific Cooperative on Phytotherapy and Thieme.

Felter HW. 1922. *The Eclectic Materia Medica, Pharmacology and Therapeutics*. Sandy (OR): Eclectic Medical Publications.

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Giacoia GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. *Clinical Therapeutics* 2008; 30(11):2097-2101.

JC 2008: Justice Canada. 2008. *Food and Drug Regulations* (C.01.021) [online]. Ottawa (ON): Justice Canada. [Accessed 2009 June 24] Available from: [http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.870/bo-ga:l\\_C-gb:s\\_C\\_01\\_001/20090622/en#anchorbo-ga:l\\_C-gb:s\\_C\\_01\\_001](http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.870/bo-ga:l_C-gb:s_C_01_001/20090622/en#anchorbo-ga:l_C-gb:s_C_01_001)



McGuffin M, Kartesz JT, Leung AY, Tucker AO. 2000. Herbs of Commerce. Silver Spring (MD): American Herbal Products Association.

Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. Amsterdam (NL): Elsevier.

Ph. Eur. 2008: European Pharmacopoeia Commission. 2008. European Pharmacopoeia, 6<sup>th</sup> edition, Volume 1. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM).

Schilcher H. 1997. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (DE): Medpharm Scientific Publishers.

USDA 2008: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [online database]. 2008. *Matricaria recutita* (L.). National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2009 July 23]. Available at: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl)

USP 32: United States Pharmacopeial Convention. 2009. United States Pharmacopeia and the National Formulary (USP 32 - NF 27). Rockville (MD): The United States Pharmacopeial Convention.

WHO 1999: World Health Organization. 1999. WHO Monographs on Selected Medicinal Plants, Volume 1. Geneva (CH): World Health Organization.

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Jensen-Jarolim E, Reider N, Fritsch R, Breiteneder H. 1998. Fatal outcome of anaphylaxis to chamomile-containing enema during labor: A case study. *Journal of Allergy and Clinical Immunology* 102(6 Pt 1):1041-1042.

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McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. *American Herbal Products Association's Botanical Safety Handbook*. Boca Raton (FL): CRC Press.

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%3fVartype%3dstarts%2bwith%26CVartype%3dstarts%2bwith%26CGenusqtype%3dstarts%2bwith%26CSpeciesqtype%3dstarts%2bwith%26Species%3drecutita%26sort%3dGenus%252cSpecies%26Speciesqtype%3dstarts%2bwith%26Genus%3dMatricaria%26Genusqtype%3dstarts%2bwith%26CSpqtype%3dstarts%2bwith>

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Ross SM. 2003. An Integrative Approach to Eczema (Atopic Dermatitis). *Holistic Nursing Practice* 17(1):56-62.

Segal R, Pilote L. 2006. Warfarin interaction with *Matricaria chamomilla*. *Canadian Medical Association Journal* 174(9):1281-1282.

USDA 2009: United States Department of Agriculture, Natural Resources Conservation Service, The PLANTS Database [online]. 2009. *Matricaria recutita* L. Baton Rouge (LA): National Plant Data Center. [Accessed 2009 June 15] Available from: <http://plants.usda.gov>



## 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)