



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.

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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 1: Dose information of *Matricaria chamomilla* dried flowers presented as dose per day

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

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 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, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2008. [Accessed 2009 June 24]. Available from: <http://www.eclecticherb.com/emp/updatesHCDI.html>

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ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. 2003. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd 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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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

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, 6th 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

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.

References reviewed:

Aronson JK, editor. 2009. Meyler's Side Effects of Herbal Medicines. Amsterdam (NL): Elsevier.

Barnes J, Anderson LA, Phillipson JD. 2007. Herbal Medicines, 3rd edition. Grayslake (IL): Pharmaceutical Press.

Crotteau CA, Towner Wright S. 2006. What is the best treatment for infants with colic? The Journal of Family Practice 55(7):634-636.

Grieve M. 1971. *A Modern Herbal*, Volume 1. New York (NY): Dover Publications; [Reprint of 1931 Harcourt, Brace & Company publication].

Heck AM, DeWitt BA, Lukes AL. 2000. Potential interactions between alternative therapies and warfarin. *American Journal of Health-System Pharmacy* 57(13):1221-1227.

Hurrell RF, Reddy M, Cook JD. 1999. Inhibition of non-haem iron absorption in man by polyphenolic-containing beverages. *British Journal of Nutrition* 81(4):289-295.

IAPT 2007: International Association of Plant Taxonomy. International Code of Botanical Nomenclature (Vienna Code) adopted by the Seventeenth International Botanical Congress Vienna, Austria, July 2005. *Regnum Vegetabile* 146 [online]. Ruggell (Liechtenstein): A.R.G. Gantner Verlag. Last updated 10.03.2007. [Accessed 2009 July 23]. Available from: <http://ibot.sav.sk/icbn/frameset/0109AppendixIIIBNSC.htm#E.%20SPERMATOPHYTA>

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>

Pereira F, Santos R, Pereira A. 1997. Contact dermatitis from chamomile tea. *Contact Dermatitis* 36(6):307.

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

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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

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.