



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.

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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:

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 (Giacoaia 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 (Giacoaia 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 \geq 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 \geq 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 1: Acceptable quantity dried equivalent

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}	\geq 15 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).



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).

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/updatesHCIDI.html>

Brinker F. 2001. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications.

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, 2nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy and Thieme.

Giacoa 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

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.

Ellingwood F. 1919. The American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications.

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



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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

- ▶ 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.