Health Canada Santé Canada

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)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
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	Dried

References: Proper name: USDA 2018; Common names: USDA 2018, McGuffin 2000 et al. 2000; Source material: Mills and Bone 2005, ESCOP 2003, Blumenthal et al. 2000, WHO 1999, Bradley 1992.

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

Subpopulation(s)		Dried flower (grams/day)	
		Minimum	Maximum
Children[1]	2-4 years	0.3	4.0
	5-9 years	0.4	6.0
	10-11 years	0.8	12.0
Adolescents[1]	12-14 years	0.8	12.0
	15-17 years	1.5	24.0
Adults[2,3]	18 years and older	1.5	24.0

[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

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.

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

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

EMEA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. [Accessed 2018 June 1]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003782.pdf

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.

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

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 2018: Justice Canada. 2018. *Food and Drug Regulations* (C.01.021) [online]. Ottawa (ON): Justice Canada. [Accessed 2018 August 8] Available from: http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-95.html#docCont

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.

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

USDA 2018: 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 2018 August 8]. Available at: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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.

Hurrel 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 camomile-containing enema during labor: A case study. Journal of Allergy and Clinical Immunology 102(6 Pt 1):1041-1042.

Madisch A, Holtmann G, Mayr G, Vinson B, Hotz J. 2004. Treatment of functional dyspepsia with herbal preparation. Digestion 69(1):45-52.

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/our-science/data/linnaean-typification/search/

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.

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