Chamomile, German - Oral

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GERMAN CHAMOMILE - MATRICARIA CHAMOMILLA Oral Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 57 KB) 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 label at the applicant's 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 to help relieve restlessness and/or nervousness (calmative) (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) Proper name(s), Common name(s), Source material(s) 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 Table 2 Footnotes Table 2 Footnote 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 Return to Table 2 footnote 1 referrer Table 2 Footnote 2 Adult dose supported by the following references: Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992. Return to Table 2 footnote 2 referrer Table 2 Footnote 3 Includes pregnant and breastfeeding women (ESCOP 2003; WHO 1999; Bradley 1992). Return to Table 2 footnote 3 referrer 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, 2 nd 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. 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MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

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.

DOSE(S)

Return to Table 2 footnote1referrer

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.

STORAGE CONDITION(S)

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

Route of Administration Oral (ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992)

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation(s)		
Matricaria chamomilla	Blue chamomileChamomileCommon chamomileGerman chamomileHungarian chamomileMedicinal chamomileFlowerMatricaria	Dried	Scented	

Subpopulation(s)	Dried Flower (grams/day)		
Minimum	Maximum		
Children1	2-4 years	0.3	4.0
5-9 years	0.4	6.0	
10-11 years	0.8	12.0	
Adolescents1	12-14 years	0.8	12.0
15-17 years	1.5	24.0	
Adults2,3	18 years and older	1.5	24.0
Table 2 FootnotesTable 2 Footnote 1Children and adolescent doses were calculated as a proportion of the adult dose (JC 2018			