Calendula - Oral

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CALENDULA - CALENDULA OFFICINALIS - 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 - 65 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 August 28, 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 Calendula officinalis Calendula Garden-marigold Marigold Pot-marigold Ruddles Scotch-marigold Calendula officinalis Flower Dried References: Proper name: USDA 2018; Common names: McGuffin et al. 2000, Wiersema and León 1999; Source material: Bradley 2006, Mills and Bone 2005. Route of Administration Oral Dosage Form(s) This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document. Use(s) or Purpose(s) Traditionally used in Herbal Medicine to help relieve inflammatory conditions of the digestive system (Bradley 2006; Hoffmann 2003; Williamson et al. 1988). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid Extract, Decoction, Infusion) 0.18 - 12 grams dried flower, per day (Bradley 2006; Mills and Bone 2005; Wichtl 2004; Hoffmann 2003; Blumenthal et al. 2000) Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/ physician if symptoms persist or worsen. Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are breastfeeding. Contraindication(s) Do not use this product if you are pregnant (Brinker 2010; Bradley 2006). Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Brinker 2010; Mills and Bone 2005). 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. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (UK): British Herbal Medicine Association; 2006. Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. USDA 2018: ARS, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). Calendula officinalis L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2008-01-11]. Available from : : http://www.ars-grin.gov/cgi- bin/npgs/html/tax_search.pl Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3rd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers; 2004 Wiersema J, Léon B. World Economic Plants: A Standard Reference. Boco Raton (FL): CRC Press LLC; 1999. Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (UK): C.W. Daniel Company Limited; 1988. References Reviewed Barnes J, Anderson LA, Phillipson JD. Herbal Medicines, 3rd edition. London (UK): Pharmaceutical Press; 2007. BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal

Medical Association; 1983. Blumenthal M. The Complete German Commission E Monographs. Austin (TX): American Botanical Council; 1998. Boon H, Smith MJ. The Complete Natural Medicine Guide to the 50 Most Common Medicinal Herbs, 2nd edition. Toronto (ON): Robert Rose Inc; 2004. Sweetman SC, editor. Martindale: The Complete Drug Reference, 35th edition. London (UK): Pharmaceutical Press; 2007. Report a problem on this page Date modified: 2019-03-01

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 for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

RISK INFORMATION

Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/ physician if symptoms persist or worsen. Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are breastfeeding. Contraindication(s) Do not use this product if you are pregnant (Brinker 2010; Bradley 2006). Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Brinker 2010; Mills and Bone 2005).

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

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation		
Calendula officinalis	CalendulaGarden-marigoldMarigoldPot-mar	ig Glad Bruddullæs Sticcitrathisma rigold	Flower	Dried