

Calendula - Buccal

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CALENDULA - CALENDULA OFFICINALIS - Buccal 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 - 46 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 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 on the label. Date March 28, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Calendula officinalis Calendula Garden-marigold Marigold Pot-marigold Ruddles Scotch-marigold Calendula officinalis Flower Dry References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013; Wiersema and León 1999; Source information: Bradley 2006; Mills and Bone 2005. Route of Administration Buccal Dosage Form(s) Acceptable dosage forms when used according to the requirements indicated in this monograph: Gargle; Loose; Mouthwash; Powder (EMA 2018; Bradley 2006). Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat (Bradley 2006; Blumenthal et al. 2000; Saunders 2000; Felter and Lloyd 1983). Notes For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Calendula is traditionally used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) Adolescents 12-17 years, Adults 18 years and older (EMA 2018). Quantity(ies) Note: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w), percentage weight by volume (% w/v) or percentage volume by volume (% v/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g., mg/mL). Loose/Powder dosage forms Methods of preparation: Dry, Powdered 100% dried flowers (EMA 2018; Bradley 2006; Saunders 2000; Felter and Lloyd 1898). Note: Powdered and dried flowers must be prepared as an infusion by the consumer prior to use (see direction for use) and must provide an equivalent of 8 to 16 milligrams dried flowers per 1 milliliter of finished product (EMA 2018). Gargle/Mouthwash dosage forms Methods of preparation: Non-Standardized Liquid Extracts (Decoction, Decoction concentrate, Fluid extract, Infusion, Infusion concentrate, Tincture) 2 - 100% of dried flower extract preparation in the finished product (Bradley 2006; Saunders 2000). Notes: The extract ratio must be between 1:1 (fluid extract) and 1:75. The formulation must be prepared in a way which is equivalent to a quantity of 8 to 16 milligrams crude dried flowers per 1 milliliter finished product. For example, for an infusion prepared with a 1:50 w/v ratio, the concentration of infusion in the finished product must be between 40 and 80% (8 - 16 mg crude dried flowers * 50 w/v (dilution) = 0.4 - 0.8 mL liquid extract in 1 mL finished product = 40 - 80% v/v extract preparation in the finished product). For a tincture prepared with a 1:5 w/w ratio, the concentration of tincture in the finished product must be between 4 and 8% (8 - 16 mg crude dried flowers * 5 w/w (dilution) = 40 - 80 mg liquid extract in 1 mL finished product = 4 - 8% w/v extract preparation in the finished product). For fluid extracts, the extract ratio must be 1:1 and the solvent must be ethanol or a mix of ethanol and water. Direction(s) for use Loose/Powder dosage forms Place [insert volume to be measured by consumer in order to obtain 1 to 2 grams dried flowers, e.g., ½ teaspoon] of product in ½ cup (125 mL) of boiling water, infuse for 10 minutes and strain. Let cool. Use 1 tablespoon (15 mL) as a mouthwash/gargle, up to 4 times per day (EMA 2018; Keukenmeester et al. 2012; Saunders 2000). Do not swallow (EMA 2018). Gargle/Mouthwash dosage forms Use 1 tablespoon (15 mL) as a mouthwash/gargle, up to 4 times per day (EMA 2018; Keukenmeester et al. 2012; Saunders 2000). Do not swallow (EMA 2018). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s)

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (EMA 2018). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days (EMA 2018). Contraindication(s) No statement required. 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 Ingredient Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. 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, 4 th edition. Sandy (OR): Eclectic Medical Publications; 2010. EMA 2018: European Medicines Agency. European Union herbal monograph on *Calendula officinalis* L., flos. 2018. [Accessed 2024, October 11]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/final-european-union-herbal-monograph-calendula-officinalis-l-flos-revision-1_en.pdf. Felter HW, Lloyd JU. King's American Dispensatory, Volume 1, 18 th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. 2nd edition. Boca Raton (FL): Taylor and Francis Group; 2013. Keukenmeester RS, Slot DE, Rosema NAM, Van der Weijden GA. Determination of a comfortable volume of mouthwash for rinsing. International Journal of Dental Hygiene 2012;10(3):169-174. McIntyre A. Herbal Treatment of Children - Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited; 2005. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Saunders PR. Herbal monograph: *Calendula officinalis* (L.), Asteraceae. The Canadian Journal of Herbalism 2000;21(1):14-17. USDA 2024: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 June 4]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Wiersema J, Léon B. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC; 1999. References Reviewed Barnes J, Anderson LA, Phillipson JD. Herbal Medicines, 3 rd 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, 2 nd edition. Toronto (ON): Robert Rose Inc; 2004. Report a problem on this page Date modified: 2019-03-01

RISK INFORMATION

Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (EMA 2018). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days (EMA 2018). Contraindication(s) No statement required. 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 Ingredient Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

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. EXAMPLE OF PRODUCT FACTS:

REFERENCES

Route of Administration Buccal

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Calendula officinalis	CalendulaGarden-marigoldMarigoldPot-marigold	Calendula officinalis Chenopodium album Chenopodium album Chenopodium album	Flower	Dry