

# Calendula - Topical

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CALENDULA - CALENDULA OFFICINALIS - Topical 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 - 89 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 May 14, 2021 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 Dried References: Proper name: USDA 2018; Common names: McGuffin et al. 2000, Wiersema and León 1999; Source information: Bradley 2006, Mills and Bone 2005. Route of Administration Topical Dosage Form(s) The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Cream; Gel; Liquid; Ointment; Salve; Solution; Spray. Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to aid in wound healing (Bradley 2006; Hoffmann 2003; Ellingwood 1983; Felter and Lloyd 1983). (Traditionally) used in Herbal Medicine to help relieve skin inflammations and irritations (Bradley 2006; Hoffmann 2003; ESCOP 2003; Blumenthal et al. 2000; Felter and Lloyd 1983). The following combined use(s) or purpose(s) is/are also acceptable: (Traditionally) used in Herbal Medicine to aid in wound healing and help relieve skin inflammations and irritations (Bradley 2006; Hoffmann 2003; ESCOP 2003; Blumenthal et al. 2000; Ellingwood 1983; Felter and Lloyd 1983). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) Children 2 to 11 years, adolescents 12 to 17 years, and adults 18 years and older (McIntyre 2005; Schilcher 1997; Bove 1996). Quantity(ies) Liquid dosage forms: Liquid, Solution, Spray Methods of preparation: Decoction, Infusion, Oil infused 90 - 100% of extract in the finished product (EMA 2018). Methods of preparation: Tincture, Fluid extract 1 - 100 % of extract in the finished product (EMA 2018; Saunders 2000). Semi-solid dosage forms: Cream, Gel, Ointment, Salve Methods of preparation: Dry, Powder 2 - 20%, dried flower, in semi-solid dosage forms (Bradley 2006, ESCOP 2003) Methods of preparation: Tincture, Fluid extract 5 - 10% of extract in semi-solid dosage forms (Bradley 2006). Note: For liquid and semi-solid dosage forms, the extracts are prepared as follows: Tincture (1:2 to 1:5); Fluid extract (1:1); Decoction or Infusion: 1-2 g of dried flower in 150-250 ml of water; Oil infused (1:10) (EMA 2018, ESCOP 2003, Saunders 2000). Direction(s) for use All products Apply to affected areas as needed. Tincture, Fluid extract (Optional) Dilute 1 part of Calendula extract with 3 parts of with freshly boiled, warm water. Soak the compress and apply to the affected areas for 30-60 minutes. Change the compress several times per day. Remove after 30-60 minutes (EMA 2018; Bradley 2006). Infusion, Decoction (Optional) Use the undiluted extract. Soak the compress and apply to the affected areas for 30-60 minutes. Change the compress several times per day. Remove after 30-60 minutes (Bradley 2006; Saunders 2000). 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 pregnant. 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 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. Bove M. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing,

Incorporated; 1996. 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. Ellingwood F. American Materia Medica, Therapeutics and Pharmacognosy, Volume 2. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1919 original]. EMA 2018: European Union herbal monograph on *Calendula officinalis* L., flos [Accessed 2021 March 31]. Available from: [https://www.ema.europa.eu/en/documents/herbal-monograph/final-european-union-herbal-monograph-calendula-officinalis-l-flos-revision-1\\_en.pdf](https://www.ema.europa.eu/en/documents/herbal-monograph/final-european-union-herbal-monograph-calendula-officinalis-l-flos-revision-1_en.pdf). ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2 nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003. Felten HW, Lloyd JU. King's American Dispensatory, Volume 1, 18 th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2 nd edition. Silver Spring (MD): American Herbal Products Association; 2000. 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. Schilcher H. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (D): Medpharm Scientific Publishers; 1997. USDA 2018: ARS, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Calendula officinalis* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 June 19]. Available from: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl) 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. Sweetman SC, editor. Martindale: The Complete Drug Reference, 35 th 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.

## 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 pregnant. 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 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 Topical

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Calendula officinalis	CalendulaGarden-marigoldMarigoldPot-marigold	Calendula officinalis Garden-marigold Marigold Pot-marigold	Flower	Dried