

NATURAL HEALTH PRODUCT

CALENDULA- *CALENDULA OFFICINALIS*

Topical

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)
<i>Calendula officinalis</i>	<ul style="list-style-type: none"> ▶ Calendula ▶ Garden-marigold ▶ Marigold ▶ Pot-marigold ▶ Ruddles ▶ Scotch-marigold 	<i>Calendula officinalis</i>	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% of 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 freshly boiled, warm water. Soak the compress and apply to the affected areas for 30-60 minutes. Change the compress several times per day (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 (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.

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