

## 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 label at the applicant's discretion.
- The solidus (/) indicates that either term and/or statement may be selected on the label.

#### Date

January 30, 2026

#### 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"> <li>• Calendula</li> <li>• Garden-marigold</li> <li>• Marigold</li> <li>• Pot-marigold</li> <li>• Ruddles</li> <li>• Scotch-marigold</li> </ul>	<i>Calendula officinalis</i>	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

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 help heal minor wounds (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).

## Notes

- The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to help heal minor wounds and help relieve skin inflammations and irritations).
- **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 heal minor wounds).
  - 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)

Children 2 to 11 years; Adolescents 12 to 17 years; Adults 18 years and older (McIntyre 2005; Schilcher 1997; Bove 1996).

### Quantity(ies)

*Liquid dosage forms: Liquid, Solution, Spray*

**Methods of preparation:** Decoction, Decoction concentrate, Infusion, Infusion concentrate, 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, Powdered

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 area(s), as needed.

*Tincture, Fluid extract (Optional)*

- Dilute 1 part of Calendula extract with 3 parts of freshly boiled, warm water and soak the compress (EMA 2018; Bradley 2006).
- Change the compress several times per day (EMA 2018; Bradley 2006).

*Infusion, decoction (Optional)*

- Use the undiluted extract and soak the compress (EMA 2018; Bradley 2006).
- Change the compress several times per day (Bradley 2006; Saunders 2000).

*Sprays*

Avoid inhaling or exposing others to spray.

**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 if** symptoms persist or worsen.

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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**

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.

<b>Product Facts</b>	
<b>Medicinal ingredient (w/w)</b> <i>Calendula officinalis</i> (Calendula – flower)	XX %
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• Traditionally used in Herbal Medicine to help heal minor wounds.</li> <li>• Traditionally used in Herbal Medicine to help relieve skin inflammations and irritations.</li> </ul>	
<b>Warnings</b>	
<b>If applicable<sup>1</sup>:</b>	
<b>Allergens: food allergen, gluten (gluten source), sulphites</b>	
<b>Contains aspartame</b>	
<b>Ask a health care practitioner before use if you are pregnant.</b>	
<b>Stop use if allergy occurs.</b>	
<b>Ask a health care practitioner if symptoms persist or worsen.</b>	
<b>Directions</b>	
Adults, adolescents and children 2 years and older: <ul style="list-style-type: none"> <li>• Apply to affected area, as needed.</li> <li>• Dilute 1 part of Calendula extract with 3 parts of freshly boiled, warm water and soak the compress<sup>2</sup></li> <li>• Change the compress several times per day<sup>2</sup></li> <li>• Use the undiluted extract and soak the compress<sup>3</sup> • Change the compress several times per day<sup>3</sup>.</li> <li>• Avoid inhaling or exposing others to spray<sup>4</sup>.</li> </ul>	
<b>Other information</b>	
(Add storage information)	
<b>Non-medicinal ingredients</b>	
List all NMIs	
<b>Questions?</b> (Call) 1-XXX-XXX-XXXX	

<sup>1</sup>This section can be removed from the table if the product contains no allergen or aspartame.

<sup>2</sup>Tincture, Fluid extract (Optional).

<sup>3</sup>Infusion, decoction (Optional).

<sup>4</sup>Sprays.

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