

NATURAL HEALTH PRODUCT

CALENDULA- *CALENDULA OFFICINALIS*

Oral

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(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 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

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