Health Canada Santé Canada

NATURAL HEALTH PRODUCT

GERMAN CHAMOMILE – *MATRICARIA CHAMOMILLA*
Buccal

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 labels at the applicants' discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date June 11, 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)
Matricaria chamomilla	▸ Blue chamomile ▸ Chamomile ▸ Common chamomile ▸ German chamomile ▸ Hungarian chamomile ▸ Matricaria ▸ Scented chamomile ▸ Scented mayweed ▸ Sweet false chamomile ▸ True chamomile ▸ Wild chamomile	*Matricaria chamomilla*	Flower	Dried

References: Proper name: USDA 2018; Common names: USDA 2018, McGuffin 2000; Source information: Mills and Bone 2005, ESCOP 2003, Blumenthal et al. 2000, WHO 1999, Bradley 1992.

Route of administration

Buccal (ESCOP 2003; Blumenthal et al. 2000; Bradley 1992)

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Dosage forms must be suited for buccal administration which allow for direct contact between the affected tissue and the medicinal ingredient (i.e. liquid preparations, gargles and mouthwashes).

Use(s) or Purpose(s)

Used in Herbal Medicine to help relieve minor inflammation and/or irritation of the mucous membranes of the mouth and/or throat (ESCOP 2003; Bradley 1992; Blumenthal et al. 2000).

Dose(s)

Subpopulation(s)

Children 6-11 years, Adolescents 12-17 years and Adults 18 years and older (Bove 2001; Schilcher 1997).

Quantity(ies)

Methods of preparation: Non-Standardised Extracts (Tincture, Fluid extract, Infusion)

- 3-10% w/v dried flower infusion (3-10 grams of dried flower in 100 milliliters of finished liquid formulation) (Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; WHO 1999; Bradley 1992).
- 1% v/v fluid extract (1 milliliters of fluid extract per 100 milliliters of finished liquid formulation) (ESCOP 2003; WHO 1999).
- 5% v/v tincture (5 milliliters of tincture per 100 milliliters of finished liquid formulation) (ESCOP 2003; WHO 1999).

Direction(s) for use

Rinse and/or gargle as needed.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Consult a healthcare practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (ESCOP 2003; Bradley 1992).

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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