

NATURAL HEALTH PRODUCT

FRANKINCENSE – *BOSWELLIA SACRA* 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 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 on the label.

DateJanuary 10, 2025

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)
<i>Boswellia sacra</i>	<ul style="list-style-type: none"> Bible frankincense Frankincense Incense Olibanum Olibanum-tree Ru xiang shu 	<i>Boswellia sacra</i>	Stem bark resin

References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013; Source information: PPRC 2020.

Route of administration

Buccal

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: Gargle; Liquid; Mouthwash.

Use(s) or Purpose(s)

Used in Traditional Chinese Medicine (TCM) to help relieve mild inflammations of the gums, mouth and throat (Bensky et al. 2004; Tierra and Tierra 1998).

Notes

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., Frankincense is used in Traditional Chinese Medicine (TCM) to help relieve mild inflammations of the gums, mouth and throat).
- 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)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powdered, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

3 – 5 grams of stem bark resin, per day (PPRC 2020).

Methods of preparation: Decoction, Decoction concentrate

3 – 10 grams of stem bark resin, per day (Bensky et al. 2004; Chen and Chen 2004).

Direction(s) for use

Gargle and/or rinse as needed.

Duration(s) of use

Ask a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use.

Risk information

Caution(s) and warning(s)

No statement required.

Contraindication(s)

Do not use if you are pregnant or breastfeeding.

Known adverse reaction(s)

No statement required.

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.

Product Facts
Medicinal ingredient in each tablespoon <i>Boswellia sacra</i> (Frankincense) X:1 extract XX mg Equivalent to YY g of stem bark resin
Uses Used in Traditional Chinese Medicine (TCM) to help relieve mild inflammations of the gums, mouth and throat.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame
Do not use if you are pregnant or breastfeeding.
Directions Adults 18 years and older: • Use 1 tablespoon (15 ml), X time(s) per day ² • Gargle and/or rinse as needed • Ask a health care practitioner for prolonged use.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

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

²Add an appropriate direction of use to indicate how to measure a single dose.

References cited

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Chen JK, Chen TT. Chinese Medical Herbology and Pharmacology. Crampton L, editor. City of Industry (CA): Art of Medicine Press Inc.; 2004.

Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. 2nd edition. Boca Ration (FL): Taylor and Francis Group; 2013.

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Li SC. Chinese Medicinal Herbs. San Francisco (CA): Georgetown Press; 1973. Long Z. The Chinese Materia Medica. Xue Yuan (China): Academy Press; 1998.

Lu H. A Comprehensive Textbook of Chinese Herbology. Vancouver (BC): Academy of Oriental Heritage; 1999.

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