

NATURAL HEALTH PRODUCT

PROPOLIS

Topical

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) 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 Product Licence Application (PLA) and product labels 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

July 31, 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)
Propolis	<ul style="list-style-type: none"> ▶ Bee propolis ▶ Feng jiao ▶ Propolis ▶ Propolis balsam ▶ Propolis resin ▶ Propolis wax 	<i>Apis mellifera</i>	Secretion

References: Proper name: Lotfy 2006, PPRC 2005; Common names: O'Neil et al. 2013, Lotfy 2006, PPRC 2005, Salatino et al. 2005, Marcucci 1995; Source material: Ramos et al. 2007, Burdock 1998.

Route of administration

Topical

Dosage form(s)

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 assist in minor wound healing (Lotfy 2006; Castalado and Capasso 2002; Peirce 1999; Tilgner 1999).

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)

0.2-0.6 grams of dried propolis, per day (PPRC 2005)

Direction(s) for use

No statement required.

Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 1 month (Jasprica et al. 2007).

Risk information

Caution(s) and warning(s)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are allergic to bee products, poplar tree products, or balsam of Peru (Brinker 2001; Marcucci 1995; Valsecchi and Cainelli 1984; Melli et al. 1983; Rudzki and Gryzwa 1983).
- ▶ Consult a health care 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 immediately if hypersensitivity/allergy occurs (Scully 2006; PPRC 2005; Hsu et al. 2004; Teraki and Shiohara 2001; Machácková 1988; Hausen et al. 1987; Valsecchi and Cainelli 1984; Melli et al. 1983; Rudzki and Grzywa 1983).

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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