

Propolis - Oral

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PROPOLIS - Oral Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 36 K)

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 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. Date May 30, 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 material(s) Part(s) Preparation(s)

Propolis Bee propolis Feng jiao Propolis Propolis balsam Propolis resin Propolis wax Apis mellifera Secretion

Dry References: Proper name: PPRC 2020; Lotfy 2006; Common names: RSC 2024; PPRC 2020; Lotfy 2006; Salatino et al. 2005; Marcucci 1995; Source information: Ramos et al. 2007; Burdock 1998. 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) Source of antioxidants/Provides antioxidants (Jasprica et al. 2007; Lotfy 2006; Kwon et al. 2004; Ichikawa et al. 2002; Tilgner 1999). Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Jasprica et al. 2007; Lotfy 2006; Kwon et al. 2004; Ichikawa et al. 2002; Tilgner 1999). (Traditionally) used in Herbal Medicine to help relieve sore throat and/or other mouth and throat infections (Castalado and Capasso 2002; Mills and Bone 2000; Tilgner 1999). 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., Propolis is traditionally used in Herbal Medicine to help relieve sore throat and other mouth and throat infections). 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) Antioxidant Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Not to exceed 0.6 grams of dried propolis, per day (PPRC 2020; Jasprica et al. 2007). Relief of sore throat/mouth and throat infections Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 0.2 - 0.6 grams of dried propolis, per day (PPRC 2020; Tilgner 1999). *Note: Solvents allowed for the method of preparation "Non-Standardized Extracts (Dry extract)" as part of this monograph are ethanol and/or water only. Direction(s) for use No statement required Duration(s) of use Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks (Jasprica et al. 2007). Risk information Caution(s) and warning(s) All uses Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are allergic to bee products, poplar tree products, or balsam of Peru (Brinker 2010; Marcucci 1995; Valsecchi and Cainelli 1984; Melli et al. 1983; Rudzki and Gryzwa 1983). Relief of sore throat/mouth and throat infections Ask 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 if hypersensitivity/allergy occurs (PPRC 2020; Scully 2006; Hsu et al. 2004; Teraki and Shiohara 2001; Machácková 1988; Hausen et al. 1987; Valsecchi and Cainelli 1984; Melli et al. 1983; Rudzki and Gryzwa 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 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.

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DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) All uses Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are allergic to bee products, poplar tree products, or balsam of Peru (Brinker 2010; Marcucci 1995; Valsecchi and Cainelli 1984; Melli et al. 1983; Rudzki and Gryzwa 1983). Relief of sore throat/mouth and throat infections Ask 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 if hypersensitivity/allergy occurs (PPRC 2020; Scully 2006; Hsu et al. 2004; Teraki and Shiohara 2001; Machácková 1988; Hausen et al. 1987; Valsecchi and Cainelli 1984; Melli et al. 1983; Rudzki and Gryzwa 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural 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:

REFERENCES

Route of administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Propolis	Bee propolisFeng jiaoPropolisPropolis balsamPropolis resinPropolis wax	Propolis	Secretion	Dry