

Propolis - Topical

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PROPOLIS-Topical 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 s) 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 information 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 Topical Dosage form(s) Acceptable dosage forms for topical use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purposes(s) (Traditionally) used in Herbal Medicine to help heal minor wounds (Lotfy 2006; Castalado and Capasso 2002; Peirce 1999; Tilgner 1999). 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., Propolis is traditionally used in Herbal Medicine to help heal minor wounds). 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 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 Apply to affected area(s), up to 4 times per day (Tilgner 1999). 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) 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). 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; Macháková 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 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. References cited Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Burdock GA. Review of the biological properties and toxicity of bee propolis (propolis). Food and Chemical Toxicology 1998;36:347-363. Castalado S, Capasso F. Propolis, an old remedy used in modern medicine. Fitoterapia 2002;73(S1):S1-S6. Hausen BM, Wollenweber E, Senff H, Post B. 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Santuccio C. Surveillance of suspected adverse reactions to natural health products: the case of propolis. *Drug Safety* 2008;31(5):419-423. Mirzoeva OK and Calder PC. The effect of propolis and its components on eicosanoid production during the inflammatory response. *Prostaglandins, Leukotrienes and Essential Fatty Acids* 1996;55(6):441-449. Murray MC, Worthington HV, Blinkhorn AS. A study to investigate the effect of a propolis-containing mouthrinse on the inhibition of de novo plaque formation. *Journal of Clinical Periodontology* 1997;24:796-798. Nakajima Y, Tsuruma K, Shinazawa M, Mishima S, Hara H. Comparison of bee products based on assays of antioxidant capacities. *BMC Complementary and Alternative Medicine* 2009;9(1):4. Santos VR, Pimenta FJGS, Aguiar MCF, do Carmo MAV, Naves MD, Mesquita RA. Short Communication: Oral Candidiasis Treatment with Brazilian Ethanol Propolis Extract. *Phytotherapy Research* 2005;19:652-654. Sforcin JM. Propolis and the immune system: a review. *Journal of Ethnopharmacology* 2007;113:1-14. Viuda-Martos M, Ruiz-Navajas Y, Fernández-López J, Pérez-Alvarez JA. Functional properties of honey, propolis, and royal jelly. *Journal of Food Science* 2008;73(9):R117-124. Vynograd N, Vynograd I, Sosnowski Z. A comparative multi-centre study on the efficacy of propolis, acyclovir and placebo in the treatment of genital herpes (HSV). *Phytomedicine* 2000;7(1):1-6. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

Use(s) or Purposes(s) (Traditionally) used in Herbal Medicine to help heal minor wounds (Lotfy 2006; Castalado and Capasso 2002; Peirce 1999; Tilgner 1999). Notes For multi-ingredient products:

RISK INFORMATION

Caution(s) and warning(s) 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). 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 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 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 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:

REFERENCES

Route of administration Topical

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