## **Propolis - Buccal**

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PROPOLIS-Buccal 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 (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 label at the applicant's discretion. The solidus (/) indicates that the terms and/or the 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 Bee propolis Feng jiao Propolis Propolis balsam Propolis resin Propolis wax Apis mellifera 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 Buccal 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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document. Use(s) or Purposes(s) (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). 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 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) All products 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. Buccal products, except those not swallowed Consult a health care practitioner/health care provider/health rinses) professional/doctor/physician prior to use if you are pregnant or breastfeeding. 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 ). References cited Brinker F. 2001. Herb Contraindications and Drug Interactions, 3 rd edition. Sandy (OR): Eclectic Medical Publications. Burdock GA. 1998. Review of the biological properties and toxicity of bee propolis (propolis). Food and Chemical Toxicology 36:347-363. Castalado S, Capasso F. 2002. Propolis, an old remedy used in modern medicine. Fitotherapia 73(S1):S1-S6. Hausen BM et al. 1987. Propolis allergy (II): the sensitizing properties of 1,1-dimethylallyl caffeic acid ester. Contact Dermatitis 17:171-177. Hsu CY, Chiang WC, Weng TI, Chen WJ, Yuan A. 2004. Laryngeal edema and anaphalactic shock after topical propolis use for acute pharyngitis. 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## **MEDICINAL INGREDIENT(S)**

Must be chosen from the currentNatural Health Products Ingredients Database (NHPID)and must meet the limitations outlined in the database. Storage conditions No statement required.

### **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 Purposes(s) (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). NoteClaims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda".

#### RISK INFORMATION

Caution(s) and warning(s) All products 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. Buccal products, except those not swallowed (e.g. gargles, rinses) Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding. 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 currentNatural Health Products Ingredients Database (NHPID)and must meet the limitations outlined in the database. Storage conditions No statement required.

# **STORAGE CONDITION(S)**

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).

## **REFERENCES**

Route of administration Buccal

Proper name(s)	Common name(s)	Source material(s)	
Proper name(s)	Part(s)		
Propolis	Bee propolisFeng jiaoPropolisPropolis balsa	nn Al <del>pio prolid</del> if <b>esi</b> n Propolis wax	Secretion