

PROPOLIS-Oral

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. It is a referenced document to be used as a labelling standard.

Note: 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.

Date: January 8, 2014

Proper name(s): Propolis (Lotfy 2006; PPRC 2005)

Common name(s):

- ▶ Propolis (Lotfy 2006; PPRC 2005)
- ▶ Bee propolis (Lotfy 2006; PPRC 2005)
- ▶ Propolis resin (Salatino et al. 2005; Marcucci 1995)

Source material(s): Secretion (of the honey bee *Apis mellifera* L.) (Apidae) (Ramos et al. 2007; Burdock 1998)

Route(s) of administration: Oral

Dosage form(s):

- ▶ Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewables (eg. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s):

Statement(s) to the effect of:

Source of antioxidants for the maintenance of good health (Jasprica et al. 2007; Lotfy 2006; PPRC 2005; 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 (PPRC 2005, Castalado and Capasso 2002, Mills and Bone 2000, Tilgner 1999)

Dose(s):

Antioxidant:

Preparation: Dry, Powder, Decoction & Infusion + All Non-Standardised Extracts

Dose(s): not to exceed 0.6 Grams per day (PRC 2005)

Relief of mouth/throat infections:

Preparation: Dry, Powder, Decoction & Infusion + All Non-Standardised Extracts

Dose(s): 0.2 - 0.6 Grams per day (PRC 2005)

Duration(s) of use:

Consult a health care practitioner for use beyond 1 month (Jasprica et al. 2007).

Risk information:

Statement(s) to the effect of:

Caution(s) and warning(s):

All uses:

Consult a health care practitioner 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).

All uses except as a source of antioxidants:

Consult a health care practitioner prior to use if you are pregnant or breastfeeding.

Consult a health care practitioner if symptoms persist or worsen.

Contraindication(s):

No statement required.

Known adverse reaction(s):

Hypersensitivity, such as allergy, has been known to occur; in which case, discontinue use immediately (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 NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

Specifications:

The finished product specifications must be established in accordance with the requirements described in the NHPD Quality of Natural Health Products Guide.

The medicinal ingredient must comply with the requirements outlined in the Natural Health Products Ingredient Database (NHPID).

The medicinal ingredient may comply with the specifications outlined in the Propolis monograph published in the Pharmacopoeia of the People's Republic of China.

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