NATURAL HEALTH PRODUCT

ROYAL JELLY

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

January 20, 2015

Proper name(s)

Royal Jelly (Sweetman 2007)

Common name(s)

Royal Jelly (Sweetman 2007)

Source material(s)

Gland secretion of worker bees (*Apis mellifera* L.) (EFSA 2011; Cherniack 2010; Guo *et al.* 2007)

Route(s) of administration

Oral

Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- 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/Provides antioxidants (Karadeniz et al. 2011; Silici et al. 2011; Viuda-Martos et al. 2008; El-Nekeety et al. 2007; Guo et al. 2007).
- Used in Herbal Medicine as a nutritive tonic (Pizzorno and Murray 2013; Peirce 1999; Bartram 1998).

Dose(s)  Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Antioxidant

Up to 6 g royal jelly, per day (Karadeniz et al. 2011; Silici et al. 2011; Viuda-Martos et al. 2008; El-Nekeety et al. 2007; Guo et al. 2007).

Nutritive tonic

0.8 – 6 g royal jelly, per day (Barnutiu et al. 2011; Stocker et al. 2005)

Duration of use

No statement required

Risk information  Statement(s) to the effect of

Caution(s) and warning(s)

If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Contraindication(s)

If you have a history of asthma or allergies, do not use this product (TGA 2001; Leung et al. 1997, 1995; Harwood et al. 1996; Laporte et al. 1996; Thien et al. 1996; Peacock et al. 1995; Bullock 1994).

Known adverse reaction(s)
Hypersensitivity, such as allergy, has been known to occur; in which case, discontinue use immediately (Leung et al. 1997, 1995; Harwood et al. 1996; Laporte et al. 1996; Thien et al. 1996; Peacock et al. 1995).

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*. In addition, according to section 3.3.9 for Antibiotic residues in bee products, the medicinal ingredient must be tested for the presence of 5-nitrofurane residues and chloramphenicol.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited


EFSA 2011. EFSA panel on dietetic products, nutrition and allergies (NDA). Scientific Opinion on the substantiation of health claims related to: anthocyanidins and proanthocyanidins; sodium alginate and ulva; vitamins, minerals, trace elements and standardized ginseng G115 extracts; vitamins, minerals, lysine and/or arginine and/or taurine; plant-based preparation for use in beverages; *Carica papaya* L.; “fish protein”; acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower...
than 3.7; royal jelly; foods low in cholesterol; and foods low in trans-fatty acids pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2083.


References reviewed


