



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 (Barnutiū *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-nitrofurans residues and chloramphenicol.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited

Barnutiu LI, Marghitas LA, Dezmirean DS, Mihai CM, Bobis O. Chemical Composition and Antimicrobial Activity of Royal Jelly – Review. *Scientific Papers: Animal Science and Biotechnologies* 2011; 44(2): 67-72.

Bartram T. *Bartram's Encyclopedia of Herbal Medicine*. London (GB): Robinson Publishing Ltd. 1998.

Bullock RJ. Fatal royal-jelly induced asthma. *Medical Journal of Australia* 1994;160:44.

Cherniack EP. Bugs as Drugs, Part 1: Insects. The “New” Alternative Medicine for the 21st Century? *Alternative Medicine Review* 2010;15(2):124-135.

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.

El-Nekeety AA, El-Kholy W, Abbas NF, Ebaid A, Amra HA, Abdel-Wahhab MA. Efficacy of royal jelly against the oxidative stress of fumonisin in rats. *Toxicon* 2007;50(2):256-269.

Harwood M, Harding S, Beasley R, Frankish PD. Asthma following royal jelly. *The New Zealand Medical Journal* 1996;109:325.

Karadeniz A, Simsek N, Karakus E, Yildirim S, Kara A, Can I, Kisa F, Emre H, Turkeli M. Royal Jelly modulates oxidative stress and apoptosis in liver and kidneys of rats treated with cisplatin. *Oxidative Medicine and Cellular Longevity* 2011;1-10.

Laporte JR, Ibañez L, Vendrell L, Ballarin E. Bronchospasm induced by royal jelly. *Allergy* 1996;51:440.

Leung R, Ho A, Chan J, Choy D, Lai CK. Royal jelly consumption and hypersensitivity in the community. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology* 1997;27(3):333-336.

Leung R, Thien FC, Baldo B. Royal Jelly-induced asthma and anaphylaxis: clinical characteristics and immunologic correlations. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology* 1995;96:1004-1007.

Peirce A. *The American Pharmaceutical Association Practical Guide to Natural Medicines*. New York (NY): William Morrow and Company Inc.; 1999.

Stocker A, Schramel P, Kettrup A, Bengsch E. Trace and mineral elements in royal jelly and homeostatic effects. *Journal of Trace Elements in Medicine and Biology* 2005; 183-189

Sweetman SC. *Martindale, The Complete Drug Reference* 2007. Pharmaceutical Press, London (GB).

Peacock S, Murray V, Turton C. Respiratory distress and royal jelly. *British Medical Journal* 1995;311:1472.

Pizzorno JE, Murray MT, editors. *Textbook of Natural Medicine*. Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006.

Silici S, Ekmekcioglu O, Kanbur M, Deniz K. The protective effect of royal jelly against cisplatin-induced renal oxidative stress in rats. *World Journal of Urology* 2011;29(1):127-132.

TGA 2001: Australian Therapeutic Goods Administration. CMEC 28: Complementary Medicines Evaluation Committee, Extracted Ratified Minutes twenty-eight Meeting, 27-28 July 2001. Australian Government Department of Health and Aging, Sydney, Australia; 2001.



[Accessed 2014 April 28]. Available from: <http://www.tga.gov.au/pdf/archive/cmec-minutes-28.pdf>

Thien FC, Leung R, Baldo BA, Weiner JA, Plomley R, Czarny D. Asthma and anaphylaxis induced by royal jelly. *Clinical and Experimental Allergy: Journal of the British Society for Allergy and Clinical Immunology* 1996;26(2):216-222.

References reviewed

Guo H, Ekusa A, Iwai K, Yonekura M, Takahata Y, Morimatsu F. Royal Jelly peptides inhibit lipid peroxidation in vitro and in vivo. *Journal of Nutritional Science and Vitaminology* 2008; 54:191-195.

Lee NJ, Fermo J. Warfarin and Royal Jelly Interaction. *Pharmacotherapy* 2006;26(4):583-586.
Morita H, Ikeda T, Kajita K, Fujioka K, Mori I, Okada H, Uno Y, Ishizuka T. Effect of royal jelly ingestion for six months on healthy volunteers. *Nutrition Journal* 2012;11:77.

Munstedt K, Henschel M, Hauenschuuld A, Von Georgi R. Royal Jelly increases high density lipoprotein levels but in older patients only. *Journal of Alternative and Complementary Medicine* 2009;15(4):329-330.

Ramadan MF, Al-Ghamdi A. Bioactive compounds and health-promoting properties of royal jelly: A review. *Journal of Functional Foods* 2012;4:39-52.

Vittek J. Effect of royal jelly on serum lipids in experimental animals and humans with arteriosclerosis. *Experientia* 1995;51(9-10):927-935.

Viuda-Martos M, Ruiz-Navajas Y, Fernandez-Lopez J, Perez-Alvarez JA. Functional properties of honey, propolis and royal jelly. *Journal of Food Science* 2008;73(9):117-124.