Royal Jelly

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ROYAL JELLY 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 PLA and product 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. 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) Royal Jelly Royal Jelly Apis mellifera Secretion References: Proper name: Sweetman 2007; Common name: Sweetman 2007; Source material: EFSA 2011, Cherniack 2010, Guo et al. 2008. Route of administration Oral 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 Purpose(s) Source of/Provides antioxidants (Karadeniz et al. 2011; Silici et al. 2011; Guo et al. 2008; Viuda-Martos et al. 2008; El-Nekeety et al. 2007). Used in Herbal Medicine as a nutritive tonic (Pizzorno and Murray 2013; Peirce 1999; Bartram 1998). Dose(s) Subpopulation Adults 18 years and older Quantity(ies) Antioxidant Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) Not to exceed 6 grams fresh royal jelly, per day (Karadeniz et al. 2011; Silici et al. 2011; Guo et al. 2008; Viuda-Martos et al. 2008; El-Nekeety et al. 2007). Nutritive tonic Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 0.8 - 6 grams fresh royal jelly, per day (Barnutiu et al. 2011; Stocker et al. 2005) Direction(s) for use No statement required Duration(s) of use No statement required Risk information Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding. Contraindication(s) Do not use this product if you have a history of asthma or allergies (TGA 2001; Leung et al. 1997; Harwood et al. 1996; Laporte et al. 1996; Thien et al. 1996; Leung et al. 1995; Peacock et al. 1995; Bullock 1994). Known adverse reaction(s) Stop use immediately if hypersensitivity/allergy occurs (Leung et al. 1997; Laporte et al. 1996; Thien et al. 1996; Leung et al. 1995; 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 . 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. 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. 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, Yildrim 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, Ibaanez 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. Peacock S, Muray V, Turton C. Respiratory distress and royal jelly. British Medical Journal 1995;311:1472. Peirce A. The American Pharmaceutical Association Practical Guide to Natural Medicines. New York (NY): William Morrow and Company Inc.; 1999. 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. 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). 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 2018 June 1]. Available from: https://www.tga.gov.au/sites/default/files/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. 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. 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, Hauenschuild 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 artherosclerosis. 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. Report a problem on this page Date modified: 2019-03-01

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.

RISK INFORMATION

Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding. Contraindication(s) Do not use this product if you have a history of asthma or allergies (TGA 2001; Leung et al. 1997; Harwood et al. 1996; Laporte et al. 1996; Thien et al. 1996; Leung et al. 1995; Peacock et al. 1995; Bullock 1994). Known adverse reaction(s) Stop use immediately if hypersensitivity/allergy occurs (Leung et al. 1997; Laporte et al. 1996; Thien et al. 1996; Leung et al. 1995; Peacock et al. 1995).

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 theNHPID.

REFERENCES

Route of administration Oral

Proper name(s)	Common name(s)	Source material(s)	
Proper name(s)	Part(s)		
Royal Jelly	Royal Jelly	Apis mellifera	Secretion