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 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)

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royal jelly</td>
<td>Royal jelly</td>
<td>Apis mellifera</td>
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<tr>
<td></td>
<td></td>
<td>Secretion</td>
</tr>
</tbody>
</table>


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(s)

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)


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


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


