NATURAL HEALTH PRODUCT

GARLIC – ALLIUM SATIVUM

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 18, 2017

Proper name(s):

Allium sativum L. (Alliaceae) (USDA 2008)

Common name(s):

Garlic (McGuffin et al. 2000)

Essential oil:
Garlic essential oil

Source material(s):

Bulb (ESCOP 2003; Bradley 1992)

Route(s) of administration:

Oral

Dosage form(s):

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
Dosage forms by age group:

- **Children 2 years**: The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacoa et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years**: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoa et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years**: The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

**Use(s) or Purpose(s):**

- Traditionally used in Herbal Medicine to help relieve the symptoms associated with upper respiratory tract infections and catarrhal conditions (Mills and Bone 2005; ESCOP 2003; Bradley 1992; Felter and Lloyd 1983 [1898]).
- Used in Herbal Medicine to help reduce elevated blood lipid levels/hyperlipidaemia in adults (Kojuri et al. 2007; Macan et al. 2006; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Blumenthal et al. 2000; Bradley 1992).

**Dose(s):**

**Table 1: Dose information for garlic bulb presented as dose per day**

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Garlic bulb (g/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>2-4 y</td>
<td>0.08</td>
<td>2</td>
</tr>
<tr>
<td>Children and adolescents</td>
<td>5-9 y</td>
<td>0.1</td>
<td>3</td>
</tr>
<tr>
<td>Adolescents</td>
<td>10-14 y</td>
<td>0.2</td>
<td>6</td>
</tr>
<tr>
<td>Adolescents and adults</td>
<td>≥ 15 y</td>
<td>0.5</td>
<td>12</td>
</tr>
</tbody>
</table>

1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of garlic in children is supported by the following references: McIntyre 2005; Schilcher 1997; Bove 2001.

2 Adult dose supported by the following references: Kojuri et al. 2006; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Blumenthal et al. 2000; Bradley 1992.

3 Includes breastfeeding women

**Table 2: Dose information for garlic essential oil presented as dose per day**

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Garlic essential oil (mg/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>≥ 19 y</td>
<td>2</td>
<td>5</td>
</tr>
</tbody>
</table>

1 Adult dose supported by the following reference: Bradley 1992.
Table 3: Dose information for allicin and alliin presented as dose per day

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Minimum (mg/day)</th>
<th>Maximum (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Allicin</td>
<td>Alliin</td>
</tr>
<tr>
<td>Children¹</td>
<td>2-4 y</td>
<td>0.17</td>
</tr>
<tr>
<td>Children and adolescents¹</td>
<td>5-9 y</td>
<td>0.25</td>
</tr>
<tr>
<td>Adolescents¹</td>
<td>10-14 y</td>
<td>0.5</td>
</tr>
<tr>
<td>Adolescents and adults¹,²,³</td>
<td>≥ 15 y</td>
<td>1</td>
</tr>
</tbody>
</table>

¹ Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of garlic in children is supported by the following references: McIntyre 2005; Schilcher 1997; Bove 2001.
² Adult dose for allicin supported by the following references: Kojuri et al. 2006; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Bradley 1992. Adult dose for alliin calculated based on the conversion ratio of 0.45 mg allicin: 1 mg alliin (ESCOP 2003).
³ Includes breastfeeding women

See Appendix 1 for examples of appropriate dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration of use:

No statement required.

Risk information:

Caution(s) and warning(s):

For relief of upper respiratory tract infections and catarrhal conditions:
- Consult a health care practitioner if symptoms persist or worsen.

For all uses:
- Consult a health care practitioner prior to use if you are pregnant (Brinker 2008; Mills and Bone 2005).
- Consult a health care practitioner prior to use if you have diabetes (Brinker 2008).
- Consult a health care practitioner prior to use if you are taking blood thinners or protease inhibitors (Brinker 2008; Mills and Bone 2005).

Contraindication(s):

No statement required.

Known adverse reaction(s):
Hypersensitivity (e.g., allergy) has been known to occur; in which case discontinue use (Brinker 2008; Mills and Bone 2005).

Non-medicinal ingredients:

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) 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 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.
- The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 4 below.
- For products containing fresh garlic in oil, the preparations must meet at least one of the following conditions in order to prevent the growth of the bacterial spores associated with botulism:
  
  i. Products are subjected to a validated treatment, such as heat treatment, with equivalent effect to the 12 D canning process (a thermal process designed to reduce the probability of survival of a single, heat-resistant spore of Clostridium botulinum by a factor of $10^{12}$) to inactivate spores of C. botulinum (FAO 1985), or
  
  ii. The water activity of the garlic bulb is reduced to 0.94 or less before adding it to the oil, or
  
  iii. Ensure that the pH of the plant material is adjusted to 4.6 or less before adding it to the oil (HC 2007).

Table 4: Garlic monographs published in British, European and US Pharmacopoeias

<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Pharmacopoeia</td>
<td>Garlic, Powdered Garlic, Powdered Garlic Extract, or Garlic Fluid Extract</td>
</tr>
<tr>
<td>European Pharmacopoeia</td>
<td>Garlic Powder Monograph</td>
</tr>
<tr>
<td>US Pharmacopoeia</td>
<td>Garlic Powder Monograph</td>
</tr>
</tbody>
</table>

References cited:


Garlic


References reviewed:


Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use

Garlic bulb:

Dried powder:

- 0.8 g, per day (Kojuri et al. 2006)
- 0.5-1 g, per day (Mills and Bone 2005; ESCOP 2003)
- 0.88 g, per day (Kannar et al. 2001)
- 4-12 g, per day (Bradley 1992)

Dried bulb:

- 2-4 g, 3 times per day (ESCOP 2003)
- 2-5 g fresh (air-dried) bulb, per day (Bradley 1992)

Infusion:

- 4 g garlic bulb, per day

**Directions for use:** Pour 150 ml of boiling water on garlic bulb and infuse.

Fluidextract:

- 6-11.5 g dried equivalent, per day
  (1:1, 6-11.5 ml) (Mills and Bone 2005)
- 4 g dried equivalent, per day
  (1:1, 4 ml) (Blumenthal et al. 2000)

Tincture:

- 1.2-2.4 g dried equivalent, per day
  (1:5, 6-12 ml) (Mills and Bone 2005)
- 0.4-0.8 g dried equivalent, 3 times per day
  (1:5, 45% ethanol, 2-4 ml) (ESCOP 2003)
- 4 g dried equivalent, per day
  (1:5, 20 ml) (Blumenthal et al. 2000)

Garlic essential oil:

- 2-5 mg, per day (Bradley 1992)

Preparations providing the following quantities of allicin:

- 1 mg, per day (Kojuri et al. 2006)
- 5-12 mg (or total thiosulphinates), per day (Mills and Bone 2005)
- 9.6 mg, per day (Kannar et al. 2001)

Preparations providing the following quantities of alliin:

- 6-10 mg (~3-5 mg of allicin), per day (ESCOP 2003)
- 4-12 mg (~2-5 mg of allicin), per day (Bradley 1992)