



## 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 label at the applicant’s discretion.
- The solidus (/) indicates that either term and/or statement may be selected on the label.

#### Date

January 30, 2026

#### Proper name(s), Common name(s), Source information

##### *Garlic dried bulb*

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Allium sativum</i>	Garlic	<i>Allium sativum</i>	Bulb	Dry

References: Proper name: USDA 2024; Common name: Gardner and McGuffin 2013; Source information: ESCOP 2003; Bradley 1992.

##### *Garlic essential oil*

Table 2. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
<i>Allium sativum</i>	Garlic essential oil	<i>Allium sativum</i>	Bulb

References: Proper name: USDA 2024; Source information: ESCOP 2003; Bradley 1992.

#### 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 by age group:

**Children 2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoaia et al. 2008; EMA/CHMP 2006).

**Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giacoaia et al. 2008; EMA/CHMP 2006).

**Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:** The acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Although delayed release dosage forms are usually not supported by the NNHPD's monographs, this monograph includes the following dosage forms commonly used for garlic products: Capsule, enteric-coated; Capsule, soft, enteric-coated; Capsule, enteric-coated pellets; Granule enteric-coated; Tablet, enteric-coated; Tablets, enteric-coated granules.

## Use(s) or Purpose(s)

- (Traditionally) used in Herbal Medicine to help relieve the symptoms associated with upper respiratory tract infections and catarrhal conditions (such as nasal congestion/buildup of excess mucus) (Mills and Bone 2005; ESCOP 2003; Bradley 1992; Felter and Lloyd 1983).
- Used in Herbal Medicine to help reduce elevated blood lipid levels (hyperlipidemia) 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).
- Used in Herbal Medicine to help maintain cardiovascular health 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).

## Notes

- The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Used in Herbal Medicine to help reduce elevated blood lipid levels and to help maintain cardiovascular health in adults).
- **For multi-ingredient products:**
  - To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Garlic is traditionally used in Herbal Medicine to help relieve the symptoms associated with upper respiratory tract infections and catarrhal conditions).



- When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required.

**Dose(s)**

**Subpopulation(s)**

As specified below.

**Quantity(ies)**

**Methods of preparation:** Dry, Powdered, Non-Standardized Extracts (Dry extract\*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

Table 3. Dose information for garlic dried bulb presented as dose (grams) per day

Subpopulation(s) <sup>1,2</sup>		Garlic dried bulb (g/day)	
		Minimum	Maximum
Children	2-4 years	0.08 g	2 g
	5-9 years	0.1 g	3 g
	10-11 years	0.2 g	6 g
Adolescents	12-14 years	0.2 g	6 g
	15-17 years	0.5 g	12 g
Adults	18 years and older	0.5 g	12 g

<sup>1</sup>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; Bove 2001; Schilcher 1997.

<sup>2</sup>Adult dose supported by the following references: Kojuri et al. 2007; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Blumenthal et al. 2000; Bradley 1992.

**\*Note:** Solvents allowed for the method of preparation “Non-Standardized Extracts (Dry extract)” as part of this monograph are ethanol and/or water only.



**Methods of preparation:** Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

Table 4. Dose information for allicin and alliin presented as dose (milligrams) per day. Extracts should be standardized to allicin and/or alliin.

Subpopulation(s) <sup>1,2</sup>		Minimum (mg/day)		Maximum (mg/day)	
		Allicin	Alliin	Allicin	Alliin
Children	2-4 years	0.17 mg	0.3 mg	2 mg	4.5 mg
	5-9 years	0.25 mg	0.5 mg	3 mg	7 mg
	10-11 years	0.5 mg	1 mg	6 mg	14 mg
Adolescents	12-14 years	0.5 mg	1 mg	6 mg	14 mg
	15-17 years	1 mg	2 mg	12 mg	27 mg
Adults	18 years and older	1 mg	2 mg	12 mg	27 mg

<sup>1</sup>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; Bove 2001; Schilcher 1997.

<sup>2</sup>Adult dose for allicin supported by the following references: Kojuri et al. 2007; 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).

**Method of preparation:** Oil, Essential (water steam distillation)

Table 5. Dose information for garlic essential oil presented as dose (milligrams) per day

Subpopulation(s)		Garlic essential oil (mg/day)	
		Minimum	Maximum
Adults <sup>1</sup>	18 years and older	2 mg	5 mg

<sup>1</sup>Adult dose supported by the following reference: Bradley 1992.

**Direction(s) for use**

No statement required.

**Combination rule**

No permitted combinations between the two medicinal ingredients listed in Tables 1 and 2.

**Duration(s) of use**

No statement required.



## Risk information

### Caution(s) and warning(s)

*Relief of upper respiratory tract infections and catarrhal (nasal congestion) conditions*

**Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.**

*All uses*

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners or protease inhibitors (Brinker 2010; Mills and Bone 2005).**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant (Brinker 2010; Mills and Bone 2005).**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Brinker 2010; Mills and Bone 2005).**

### Contraindication(s)

No statement required.

### Known adverse reaction(s)

**Stop use if hypersensitivity/allergy occurs (Brinker 2010; 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.

## Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

## 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.



**EXAMPLE OF PRODUCT FACTS:**

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

<b>Product Facts</b>	
<b>Medicinal ingredient</b> in each capsule	
<i>Allium sativum</i> (Garlic – bulb)	XX mg
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• Traditionally used in Herbal Medicine to help relieve the symptoms associated with upper respiratory tract infections and catarrhal conditions.</li> <li>• Used in Herbal Medicine to help reduce elevated blood lipid levels and to help maintain cardiovascular health in adults.</li> </ul>	
<b>Warnings</b>	
<b>If applicable<sup>1</sup>:</b>	
<b>Allergens: food allergen, gluten (gluten source), sulphites</b>	
<b>Contains aspartame</b>	
<b>Ask a health care practitioner before use if</b> • you are taking blood thinners or protease inhibitors • you are pregnant • you have diabetes.	
<b>Stop use if</b> allergy occurs.	
<b>Ask a health care practitioner if</b> symptoms persist or worsen.	
<b>Directions</b>	
Adults 18 years and older: Take X capsule(s), X time(s) per day.	
<b>Other information</b>	
(Add storage information)	
<b>Non-medicinal ingredients</b>	
List all NMIs	
<b>Questions?</b> (Call) 1-XXX-XXX-XXXX	

<sup>1</sup>This section can be removed from the table if the product contains no allergen or aspartame.

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