Garlic

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Garlic - Allium sativum (PDF Version - 115 K) 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 the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant on the label. Date March 28, 2025 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) Allium sativum Garlic Allium sativum Bulb Dry References: Proper name: USDA 2024; Common name: Gardner and McGuffin et al. 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) Allium sativum Garlic essential oil Allium sativum 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 (Giacoia 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 (Giacoia 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. 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) 1 , 2 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 above 0.5 g 12 g 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; Bove 2001; Schilcher 1997. 2 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) 1 , 2 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 above 1 mg 2 mg 12 mg 27 mg 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; Bove 2001; Schilcher 1997. 2 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 1 18 years and above 2 mg 5 mg 1 Adult dose supported by the following reference: Bradley 1992. Direction(s) of 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. References cited Blumenthal M, Goldberg A, Brinkmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000. Bove M. An Encyclopedia of Natural Healing for Children & Infants, 2 nd edition. Toronto (ON): McGraw-Hill; 2001. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (UK): British Herbal Medicine Association; 1992. Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. [Accessed 2024 December 15]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf ESCOP: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2 nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003. Felter HW, Lloyd JU. King's American Dispensatory, Volume 1, 18 th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. Second Edition. Boca Ration (FL): Taylor and Francis Group; 2013. Giacoia GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. Clinical Therapeutics 2008; 30(11):2097-2101. JC 2008: Justice Canada. Food and Drug Regulations C.01.021. Ottawa (ON): Justice Canada. [Accessed 2024 December 15]. Available from: http://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-110.html#h-156 Kannar D, Wattanapenpaiboon N, Savige G, Wahlqvist M. Hypocholesterolemic effect of an enteric-coated garlic supplement. Journal of the American College of Nutrition 2001;20(3):225-231. Kojuri J, Vosoughi A, Akrami M. Effects of anethum graveolens and garlic on lipid profile in hyperlipidemic patients. Lipids in Health and Disease 2007;6(5):1476-1511. Macan H, Uykimpang R, Alconel M, Takasu J, Razon R, Amagase H, Niihara Y. Significance of garlic and its constituents in cancer and cardiovascular disease: aged garlic extract may be safe for patients on warfarin therapy. Journal of Nutrition 2006;136:793S-795S. McIntyre A. Herbal Treatment of Children - Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited; 2005. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Schilcher H. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (D): Medpharm Scientific Publishers; 1997. USDA 2024: United States Department of Agriculture, Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 December 15]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch

References reviewed BHP: British Herbal Pharmacopoeia. Bournemouth (UK): British Herbal Medicine Association; 1996. Budoff M. Aged garlic extract retards progression of coronary artery calcification. The Journal of Nutrition 2006;136(3 Suppl):741S-744S. CDC 2007: Centers for Disease Control and Prevention. Update: International Outbreak of Restaurant-Associated Botulism -- Vancouver, British Columbia, Canada. Morbidity and Mortality Weekly Report (MMWR) October 18, 1985 / 34(41);643. Atlanta (GA): Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services. [Accessed 2024 December 15]. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/00000627.htm Gardner CD, Lawson LD, Block E, Chatterjee LM, Kiazand A, Balise RR, Kraemer HC. Effect of raw garlic vs commercial garlic supplements on plasma lipid concentrations in adults with moderate hypercholesterolemia. Archives of Internal Medicine 2007;167(4):346-353. HC 2008: Health Canada. Health Products and Food Branch (HPFB) Standards and Guidelines for Microbiological Safety of Food - An Interpretive Summary. Ottawa (ON): Food Directorate Evaluation Division, Bureau of Microbial Hazards, Health Canada. [Accessed 2024 December 15]. Available from: https://canadianpackagedice.org/wp-content/uploads/2023/08/Health_Canada_Interpetive_Summary_for_Micro_2008-1.pdf Lund B. Quantification of factors affecting the probability of development of pathogenic bacteria, in particular Clostridium botulinum, in foods. Journal of Industrial Microbiology 1993;12(3-5):144-155. Mills S, Bone K. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone; 2000. NIH 2024a: National Institutes of Health. PubChem. Alliin; RN: 556 27 4. Bethesda (MD): National Library of Medicine, US Department of Health & Human Services. [Accessed 2024 December 15]. Available from: https://pubchem.ncbi.nlm.nih.gov/ NIH 2024b: National Institutes of Health. PubChem. Allicin; RN: 539 86 6. Bethesda (MD): National Library of Medicine, US Department of Health & Human Services. [Accessed 2024 December 15]. Available from: https://pubchem.ncbi.nlm.nih.gov/ NIH 2024c: National Institutes of Health. PubChem. S-allylcysteine; RN: 21593 77 1. Bethesda (MD): National Library of Medicine, US Department of Health & Human Services. [Accessed 2024 December 15]. Available from: https://pubchem.ncbi.nlm.nih.gov/ Ziaei S, Hantoshzadeh P, Rezasoltani P, Lamyian M. The effect of garlic tablet on plasma lipids and platelet aggregation in nulliparous pregnants at high risk of preeclampsia. European Journal of Obstetrics & Gynecology and Reproductive Biology 2001;99(2):201-206. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

Acceptable dosage forms by age group: Children 2 years:The acceptable dosage forms are limited to emulsion/suspension and solution/ liquid preparations (Giacoia 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 (Giacoia 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.

DOSE(S)

*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)1,2Minimum (mg/day)Maximum (mg/day)AllicinAlliinAllicinAlliinChildren2-4 years0.17 mg0.3 mg2 mg4.5 mg5-9 years0.25 mg0.5 mg3 mg7 mg10-11 years0.5 mg1 mg6 mg14 mgAdolescents12-14 years0.5 mg1 mg6 mg14 mg15-17 years1 mg2 mg12 mg27 mgAdults18 years and above1 mg2 mg12 mg27 mg

NON-MEDICINAL INGREDIENTS

Must be chosen from the currentNatural Health Products Ingredients Database(NHPID) and must meet the limitations outlined in the database.

STORAGE CONDITION(S)

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.

REFERENCES

Garlic essential oil Table 2. Proper name(s), Common name(s), Source informationProper name(s)Common name(s)Source informationSource material(s)Part(s)Allium sativumGarlic essential oilAllium sativumBulb References: Proper name: USDA 2024; Source information: ESCOP 2003; Bradley 1992.

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

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

Subpopulation(s)1,2	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 above	0.5 g	12 g

Subpopulation(s)1,2	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 above	1 mg	2 mg	12 mg	27 mg

Subpopulation(s)	Garlic essential oil (mg/day)		
Minimum	Maximum		
Adults1	18 years and above	2 mg	5 mg