EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Allium sativum* L., bulbus

Draft

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	January 2013 March 2013 July 2013 March 2014 July 2015 February 2016 April 2016
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Rediscussion in MLWP	
Adoption by HMPC	

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BG (bulgarski): Чесън, луковица	LT (lietuvių kalba): Česnakai
CS (čeština): česneková cibule	LV (latviešu valoda): Ķiploka sīpols
DA (dansk): Hvidløg	MT (Malti): Basla tat-Tewm
DE (Deutsch): Knoblauchzwiebel	NL (Nederlands): Knoflook
EL (elliniká): Βολβός σκορόδου	PL (polski): Czosnek
EN (English): Garlic	PT (português): Alho, bolbo de
ES (español): Ajo, bulbo de	RO (română): bulb de usturoi
ET (eesti keel): küüslauk	SK (slovenčina): Cibuľa cesnaku (cesnak)
FI (suomi): valkosipuli	SL (slovenščina): čebulica česna
FR (français): Ail (bulbe d')	SV (svenska): Vitlök, lök
HR (hrvatski): češnjakova lukovica	IS (íslenska):
HU (magyar): fokhagyma	NO (norsk): Hvitløk
IT (italiano): Aglio bulbo	

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European Union herbal monograph on *Allium sativum* L., bulbus

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Allium sativum* L., bulbus; (garlic) i) Herbal substance Not applicable ii) Herbal preparations a) Powdered herbal substance b) Liquid extract from fresh bulb (DER 2-3:1), extraction solvent rapeseed oil, refined c) Dry extract (DER 5:1), extraction solvent ethanol 34% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[2] The material complies with the Ph. Eur. monograph (ref.: 12163)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product used as an adjuvant for the prevention of atherosclerosis. Indication 2) Traditional herbal medicinal product used for the relief of the symptoms of cold. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Indication 1) *Adults and elderly* a) Powdered herbal substance single dose: 300 mg to 750 mg Daily dose: 900-1380 mg divided into 3 to 5 b) Liquid extract: Single doses: 110-220 mg 4 times daily Daily dose: 440-880 mg The use in children and adolescents under 18 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’). Indication 2) *Adolescents, adults and elderly* c) Dry extract: Single dose: 100-200 mg 1-2 times daily Daily dose: 100-400 mg The use in children under 12 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).

Well-established use	Traditional use
	Duration of use Indication 1) No restrictions to the duration of use. Indication 2) If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. Patients under saquinavir/ritonavir therapy (see also section 4.5 Interactions).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
.	Garlic consumption should be avoided 7 days before surgery because of the post-operative bleeding risk. Indication 1) The use in children and adolescents under 18 years of age has not been established due to lack of data. Indication 2) The use in children under 12 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	Garlic preparations should be used with caution in patients taking oral anticoagulation therapy and/or anti-platelet therapy because they may increase bleeding times. Concomitant use with saquinavir/ritonavir is contraindicated because of the risks of decrease in plasma concentration, loss of virological response and possible resistance to one or more components of the antiretroviral regime (see also section 4.3 Contraindications).

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. Studies in animals have shown effects on fertility (see section 5.3 'Preclinical safety data').

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	- Malodorous breath or body odour, abdominal pain, bloating, flatulence, fullness, anorexia - Allergic reactions such as contact dermatitis, conjunctivitis, rhinitis, or bronchospasms, sometimes severe - Headache, dizziness, and profuse sweating - Bleeding The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care

Well-established use	Traditional use
	practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Adequate tests on reproductive toxicity and genotoxicity have not been performed. Tests on carcinogenicity have not been performed. Testicular toxicity (e.g. spermatogenesis impairment) was reported in rats treated for 30 days with crude garlic and in rats treated for 70 days with 50 mg of garlic powder. A decrease in testosterone occurs concomitantly; a NOAEL was not determined for the garlic powder. These effects on male rat fertility were observed at approximately twice the maximal human daily dose.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation / last revision

12 July 2106