EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Leonurus cardiaca* L., herba

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2010
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; L*eonurus cardiaca* L., herba; Leonuri cardiacae herba, motherwort

BG (bălgarski): Стрък от дяволска уста
CS (čeština): srdečníková nať
DA (dansk): Hjertespand
DE (Deutsch): Herzgespannkraut
EL (elliniká): Λεοντόνουρος ο καρδιακός
EN (English): Motherwort
ES (espanol): AGRIPALMA, partes aéreas floridas de
ET (eesti keel): lääne-südamerohu ürt
FI (suomi): Nukula
FR (français): Agripaume (parties aériennes d')
HU (magyar): szúrós gyöngyajak virágos hajtás (szu'ro's gyo¨ngyajak)
IT (italiano): Cardiaca comune
LT (lietuvių kalba): Sukatžolių žolė
LV (latviešu valoda): Sirds māteres laksts
MT (malti): Kardiaka komuni
NL (nederlands): Hartgespan, Hartkruid
PL (polski): Ziele serdecznika
PT (português):
RO (română): iarbă de talpa gâştei
SK (slovenčina): Vňať srdcovníka obyčajného
SL (slovenščina): Deljenolistna srčnica
SV (svenska): Hjärtstilla ört
IS (íslenska):
NO (norsk): Hjerteurt

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Community herbal monograph on *Leonurus cardiaca* L., herba

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 *Leonurus cardiaca* L., herba (motherwort) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% V/V d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% V/V e) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Tinctures and liquid extract in liquid dosage forms for oral use. Powdered herbal substance for oral use. Comminuted herbal substance as herbal tea for oral use.

1 The material complies with the Ph. Eur. monograph (ref.: 01/2008:1833)
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product used to relieve symptoms of nervous tension. Indication 2) Traditional herbal medicinal product used to relieve symptoms of nervous cardiac complaints such as palpitations, after serious conditions have been excluded by a medical doctor. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and elderly* a) Comminuted herbal substance for tea preparation: single dose 1.5 to 4.5 g, daily dose 3 to 10 g. b) Powdered herbal substance: single dose 150 mg, 1-3 times per day. c) Tincture 1:5, ethanol 70% V/V: single dose 0.5- 1.0 g, 3-4 times per day. d) Tincture 1:5, ethanol 45% V/V: single dose 2-6 ml, 3 times per day. e) Liquid extract: single dose 2-4 ml, 3 times per day. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').

Well-established use	Traditional use
	Duration of use If the symptoms persist longer than 4 weeks 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. Not to be used in pregnancy.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 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. Tinctures, liquid extract: the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	Contraindicated during pregnancy. The safety during lactation has not been

	established.

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. May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions occur, a doctor or a qualified health care 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 have not been performed. Tests on genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	**Traditional use**
	Not applicable.

7. Date of compilation/last revision

16 September 2010