EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2012
EMA/HMPC/337066/2011
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia* x *vulgaris* Heyne or their mixtures, flos

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2011 July 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	13 September 2011
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 February 2012
Rediscussion in Working Party on Community monographs and Community list (MLWP)	March 2012
Adoption by Committee on Herbal Medicinal Products (HMPC)	22 May 2012

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Tilia cordata* Miller, *Tila platyphyllos* Scop., *Tilia* x *vulgaris* Heyne or their mixtures, flos; Tiliae flos; Lime flower

BG (bălgarski): Липа, цвят	LT (lietuvių kalba):
CS (čeština): Lipový květ	LV (latviešu valoda): Liepu ziedi
DA (dansk): Lindeblomst	MT (malti):
DE (Deutsch): Lindenblüten	NL (nederlands): Lindebloesem
EL (elliniká): Άνθος φιλλύρας	PL (polski): Kwiat lipy
EN (English): Lime flower	PT (português): Tília, flor
ES (espanol): Tilo, flor de	RO (română): Floare de tei
ET (eesti keel): Pärnaõis	SK (slovenčina): Lipový kvet
FI (suomi): Hopealehmus, kukka	SL (slovenščina): Cvet lipe
FR (français): Tilleul (fleur de)	SV (svenska): Lindblomma
HU (magyar): Hársfavirágzat	*IS (íslenska)*:
IT (italiano): Tiglio fiore	*NO (norsk):* Lindeblomst

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Community herbal monograph on *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia* x *vulgaris* Heyne or their mixtures, flos

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 *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia* x *vulgaris* Heyne or their mixtures, flos (lime flower) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid 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.: 01/2008:0957).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product used for the relief of symptoms of common cold. Indication 2) Traditional herbal medicinal product for the relief of mild symptoms of mental stress. 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[3]

Well-established use	Traditional use
	Posology *Adolescents, Adults and Elderly* Indications 1) and 2) a) Comminuted herbal substance Single dose Herbal tea: 1.5 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 2–4 times daily. Daily dose: 3-6 g b) Liquid extract Single dose: 2 ml, 1-2 times daily Daily dose: 2-4 ml c) Tincture Single dose: 1 ml, 1-2 times daily Daily dose: 1-2 ml

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	Indication 1) *Children between 4 and 12 years of age* a) Comminuted herbal substance Single dose Herbal tea: 1 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 2–4 times daily. Daily dose: 2-4 g The use in children under 4 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2) The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) The therapy should start at first signs of common cold. If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 2) If the symptoms persist 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.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	For tinctures and extracts containing ethanol, 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. Indication 1) The use in children under 4 years of age has not been established due to lack of adequate data. Indication 2) The use in children under 12 years of age has not been established due to lack of adequate data. Indication 1) If the symptoms worsen during the use of the medicinal product or if dyspnoea, high fever or purulent sputum occurs, 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
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	No fertility data available. Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

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
	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 genotoxicity have not been performed. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation / last revision

22 May 2012