EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2014
EMA/HMPC/669740/2013
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Passiflora incarnata* L., herba

Final

Initial assessement	
Discussion in Working Party on Community monographs and Community list (MLWP)	October 2006 January 2007 March 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	8 March 2007
End of consultation (deadline for comments).	15 June 2007
Rediscussion in MLWP	September 2007
Adoption by HMPC Monograph (EMEA/HMPC/230962/2006) AR (EMEA/HMPC/230961/2006) List of references (EMEA/HMPC/111180/2007) Overview of comments received during the public consultation (EMEA/HMPC/383450/2007) HMPC Opinion (EMEA/HMPC/405535/2007)	7 September 2007
First systematic review	
Discussion in MLWP	November 2013 January 2014
Adoption by HMPC for release for consultation	N/A
End of consultation (deadline for comments)	N/A
Rediscussion in MLWP	N/A
Adoption by HMPC	25 March 2014

A search for the versions adopted in September 2007 can be made via the EMA document search function, using the documents' reference number, at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid=

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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Passiflora incarnata* L.; Passiflorae herba; Passion Flower.

BG (bălgarski): Пасифлора, стрък **CS (čeština):** Mučenková nať **DA (dansk):** Passionsblomst **DE (Deutsch):** Passionsblumenkraut **EL (elliniká):** Παθοβότανο **EN (English):** Passion Flower **ES (espanol):** Pasiflora, partes aéreas de **ET (eesti keel):** Kannatuslilleürt **FI (suomi):** Kärsimyskukka **FR (français):** Passiflore (parties aériennes de) HR (hrvatska): Pasiflorova zelen **HU (magyar):** Észak-amerikai golgotavirág hajtás **IT (italiano):** Passiflora parti aeree	**LT (lietuvių kalba):** Pasiflorų žolė **LV (latviešu valoda):** Pasifloras laksti **MT (malti):** Fjura Tal-Passjoni **NL (nederlands):** Passiflora **PL (polski):** Ziele męczennicy **PT (português):** Passiflora **RO (română):** Iarbă de floarea patimilor **SK (slovenčina):** Mučenková vňať **SL (slovenščina):** Zel zdravilne pasijonke **SV (svenska):** Passionsblomma ***IS (íslenska)*:** ***NO (norsk):*** Pasjonsblomst

Community herbal monograph on *Passiflora incarnata* 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 *Passiflora incarnata* L., herba (Passion flower) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:8) extraction solvent ethanol 25% V/V d) Liquid extract (DER 1:8) extraction solvent ethanol 45% V/V e) Liquid extract (DER 1:3.6) extraction solvent ethanol 60% V/V f) Liquid extract (DER 1:1) extraction solvent ethanol 25% V/V g) Liquid extract (DER 1:1) extraction solvent ethanol 70% V/V h) Liquid extract (DER 1:3.8-4.3) extraction solvent ethanol (96% V/V) + glycerol (85% m/m) + Water (11.8 + 1 + 7.9) Dried extracts corresponding to the tea and liquid extracts above.

[1]The material complies with the Eur.Ph.monograph (ref. 01/2005:1364)

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

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral 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**
	Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep. 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[3]

Well-established use	**Traditional use**
	Posology *Adolescents, adults and elderly* Single dose ii) Herbal preparations a) Herbal tea: 1-2 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 1-4 times daily b) Powdered herbal substance: 0.5-2g, 1-4 times daily c) Liquid extract: 2-4 ml, up to 4 times daily d) Liquid extract: 2 ml, up to 3 times daily e) Liquid extract: 1 ml, 3-5 times daily f) Liquid extract: 0.5-2 ml, up to 4 times daily g) Liquid extract: 2 ml up to 3 times daily

[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**
	h) Liquid extract: 0.3-0.4 ml, adults 3-5 times daily; adolescents 3 times daily Doses of dried extracts corresponding to the posologies of tea and liquid extracts above. 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** If the symptoms persist longer than 2 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.

4.4. Special warnings and precautions for use

Well-established use	**Traditional use**
	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. For liquid 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.

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

4.7. Effects on ability to drive and use machines

Well-established use	**Traditional use**
	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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

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

7. Date of compilation / last revision

25 March 2014