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*Evaluation of Medicines for Human Use*



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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)**

**FINAL**

# COMMUNITY HERBAL MONOGRAPH ON *PASSIFLORA INCARNATA* L., HERBA

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| **DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)** | October 2006<br>January 2007<br>March 2007 |
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# 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 marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended | With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended<br><br>*Passiflora incarnata* L., herba (passion flower)<br><br>i) Herbal substance<br>Fragmented or cut, dried aerial parts<br><br>ii) Herbal preparations<br>Herbal substance for tea preparation<br>Liquid extract (1:8 ; extraction solvent 25% ethanol)<br>Liquid extract (1:8 ; extraction solvent 45% ethanol)<br>Liquid extract (1:1 ; extraction solvent 25% ethanol)<br>Liquid extract (1:1 ; extraction solvent 70% ethanol)<br><br>iii) Corresponding dry extracts |

## 3. PHARMACEUTICAL FORM

| Well-established use | Traditional use |
|---|---|
| | Herbal substance or herbal preparations in solid or liquid dosage forms for oral use.<br><br>The pharmaceutical form should be described by the European Pharmacopoeia full standard term. |

[1] The material complies with the Ph. Eur. monograph (ref. 01/2005:1459).

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

## 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.<br><br>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use. |

### 4.2. Posology and method of administration

| Well-established use | Traditional use |
|---|---|
| | **Posology**<br><br>*Adolescents over 12 years of age, adults*<br>0.5-2 g of herbal substance as powder 1-4 times daily.<br>To make an infusion, pour 150 ml of boiling water over 1–2 g of herbal substance. Steep for 10 minutes. To be taken 1-4 times daily.<br>2-4 ml of liquid extract (1:8 ; extraction solvent 25% ethanol) up to 4 times daily.<br>2 ml of liquid extract (1:8 ; extraction solvent 45% ethanol) up to 3 times daily.<br>0.5-2 ml of liquid extract (1:1 ; extraction solvent 25% ethanol) up to 4 times daily.<br>2 ml of liquid extract (1:1 ; extraction solvent 70% ethanol) up to 3 times daily.<br><br>Corresponding doses of dry extracts.<br><br>The use in children under 12 years of age is not recommended (see section 4.4 Special warnings and precautions for use).<br><br>**Duration of use**<br><br>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.<br><br>**Method of administration**<br><br>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 is not recommended because data are not sufficient and medical advice should be sought.<br><br>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 |
|---|---|
| | Although no clinical data about interactions with synthetic sedatives are available, concomitant use with synthetic sedatives (such as benzodiazepines) is not recommended unless advised by a doctor. |

### 4.6. Pregnancy and lactation

| Well-established use | Traditional use |
|---|---|
| | Safety during pregnancy and lactation has not been established.<br>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 |
|---|---|
| | 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 |
|---|---|
| | One case of hypersensitivity (vasculitis) and one case of nausea and tachycardia have been reported. The frequency is not known.<br>If other adverse reactions not mentioned above 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.<br><br>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

7 September 2007