



The European Agency for the Evaluation of Medicinal Products  
*Evaluation of Medicines for Human Use*

31 March 2000  
EMA/HMPWP/18/00

## **WORKING PARTY ON HERBAL MEDICINAL PRODUCTS**

### **DRAFT PROPOSAL FOR A CORE DATA FOR PASSION FLOWER**

|                                                           |                                    |
|-----------------------------------------------------------|------------------------------------|
| DISCUSSION IN THE HERBAL MEDICINAL PRODUCTS WORKING PARTY | May 1999, October 1999, March 2000 |
| RELEASE FOR CONSULTATION BY THE EMA                       | May 2000                           |
| DEADLINE FOR COMMENTS                                     | August 2000                        |
| RE-SUBMISSION TO THE HMPWP                                | October 2000                       |

*The views presented in this document are those of the HMPWP, which has been created as a forum for exchange of experience in the field of herbal medicinal products. This document is released for the purposes of transparency and has no legal force with respect to Directive 2001/83/EC.*

## **Draft proposal for a core-data for Passion flower**

The Working Group on Herbal Medicinal Products proposes the following core-data for *Passion flower*<sup>1</sup> (March 2000).

### **1. NAME OF THE MEDICINAL PRODUCT**

To be specified for the individual finished product.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>2</sup>**

Passionflower herb

Liquid extract, ethanolic 25% (1:1)

Tincture, ethanolic 25% (1:8)

### **3. PHARMACEUTICAL FORM**

Herbal drug preparation in solid or liquid dosage forms (to be labelled according to the standard terms published by the European Pharmacopoeia).

### **4. CLINICAL PARTICULARS**

#### **4.1. Therapeutic indications**

Herbal medicinal product for the relief of temporary mild nervous tension.

#### **4.2. Posology and method of administration**

For oral use

Adults, elderly and children over 12 years of age

2-4 times daily:

0.5-2 g of the dried herb

2 g of finely chopped drug as infusion

Tincture, ethanolic 25% (1:8), 2-4ml

Liquid extract, ethanolic 25% (1:1), 0.5-2 ml

#### **4.3. Contraindications**

None known

#### **4.4. Special warning and precautions for use**

Because there is no experience available, the use is not recommended in children younger than 12 years of age.

#### **4.5. Interaction with other medicinal products and other forms of interaction**

None reported

---

<sup>1</sup> The herbal drug complies with European Pharmacopoeia

<sup>2</sup> The declaration of all active substances should be done in accordance with the Note for Guidance on quality of herbal medicinal products (type A.1.i or type A.2.1) as revised by the Ad Hoc Working Group on Herbal Medicinal Products  
EMEA/HMPWP/18/00

#### **4.6. Pregnancy and lactation**

Because data on the use during pregnancy and lactation are not available, the use is not recommended as a general precaution.

#### **4.7. Effects on ability to drive and use machines**

Intake of passionflower preparations immediately (up to two hours) before driving a car or operating machinery is not recommended.

#### **4.8. Undesirable effects**

No adverse effect known to date under the recommended conditions of short term use.

#### **4.9. Overdose**

Not reported.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1. Pharmacodynamic properties**

Pharmacotherapeutic group: Hypnotics and sedatives, ATC code: N05C M

Sedative effects of preparations of passionflower herb such as tea infusions and tinctures have long been recognised empirically but cannot be attributed with certainty to any known constituents. 1. The therapeutic use of passionflower herb is based on well-established use supported by results of pharmacological studies in animals. (Evidence level IV).

#### **5.2. Pharmacokinetic properties**

No pharmacokinetic data available.

#### **5.3. Preclinical safety data**

No systematic investigations available. The bibliographic data and long-term use do not give any reasons for concern.