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

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WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

DRAFT PROPOSAL FOR A CORE DATA FOR MELISSA LEAF

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Draft proposal for a core-data for Melissa leaf

The Working Group on Herbal Medicinal Products proposes the following core-data for *Melissa leaf*[1] (March 2000).

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[2]

Melissa leaf
Liquid extract, ethanolic 45% (1:1)
Tincture, ethanolic 45% (1:5)

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
2-3 g of the drug as infusion, 2-3 times daily
Liquid extract, ethanolic 45% (1:1), 2-4 ml three times daily
Tincture, ethanolic 45% (1:5), 2-6 ml three times daily

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.

[1] The herbal drug complies with European Pharmacopoeia

[2] 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

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 melissa 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

The sedative effects of preparations of melissa leaf such as tea infusions or tincture have long been recognised empirically but cannot be attributed with certainty to any known constituents. 1. These uses are made plausible by pharmacological data. (Evidence level IV).

5.2. Pharmacokinetic properties

No pharmacokinetic data available.

5.3. Preclinical safety data

No mutagenicity was demonstrated in a tincture (ethanol 70%, 1:5) of melissa leaf in the Salmonella microsome reversion assay (Ames test).