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

17 September 1998
EMEA/HMPWP/14/99

AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS

Final Proposal for a Core Data for Valerianae Radix

RELEASE FOR CONSULTATION BY THE EMEA	January 1998
DEADLINE FOR COMMENTS	April 1998
RELEASE OF FINAL PROPOSALS	September 1998

Note:

Modifications from the original texts proposed by the group are in *bold italic.*

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.eu.int http://www.emea.eu.int

Final Proposal for a core-data for *Valerianae radix* -

The working group proposes the following core-data for *Valeriane radix*[1] (July 1998)

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[2]

Valerian root
Extract prepared with water, ethanol/water (max 70%)
Tinctures (1:5, ethanol max 70% V/V)

3. PHARMACEUTICAL FORM

Herbal drug or 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 and temporary difficulty in falling asleep (see Section 4.4 Special warnings and special precautions for use).

4.2. Posology and method of administration

For oral use

Adults and children over 12 years
Single dose:
2 to 3 g of the drug (e.g. as herbal tea).
1 to 3 ml of tincture (1:5, ethanol max 70% V/V).
Extracts with water, ethanol/water (max 70%) equivalent to 2 to 3 g of the drug.
For nervous tension up to 3 time daily.
As an aid to sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

Elderly: As for adults.

4.3. Contra-indications

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

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1 The herbal drug complies with the European Pharmacopoeia

2 The declaration of all active substances should be done in accordance to the Note for guidance on quality of herbal medicinal products (type A.1.i or type A.2.i.) as revised by the ad hoc Working Group on Herbal Medicinal Products

4.4. Special warnings and special precautions for use

Please note that the Patient Leaflet invites the patient to seek medical advice if symptoms persist for more than 2 weeks or worsen.

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

None reported.
If the patient is on other medication he/she is invited to seek medical advice.

4.6. Use during pregnancy and lactation

Because data on the use during pregnancy and lactation are not available, the use is not recommended as a general precaution. No adverse effects have been reported from the common use of Valerian roots as a medicinal product but experimental data are lacking.

4.7. Effects on ability to drive and use machines

Intake of valerian preparations immediately (up to two hours) before driving a car or operating machinery is not recommended. The effect of valerian preparations may be enhanced by consumption of alcohol.

4.8. Undesirable effects

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

4.9. Overdose

Valerian root at a dose of approximately 20 g caused benign symptoms (fatigue, abdominal cramp, chest tightness, lightheadedness, hand tremor and mydriasis) which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Hypnotics and sedatives, ATC code: N05C M09

The sedative effects of preparations of Valerian roots such as tea-infusions or tincture have long been recognised empirically but cannot be attributed with certainty to any known constituents. Orally administered dry extracts of valerian root prepared with water have been shown to improve sleep latency and sleep quality in man, although the statistical significance in these studies was more apparent from subjective evaluations than from objective measures of sleep.

5.2. Pharmacokinetic properties

No pharmacokinetic data available.

5.3. Preclinical safety data[1]

Extracts with ethanol and the essential oil of Valerian root have shown low toxicity in rodents during acute test and from repeated dose toxicity over periods of 4-8 weeks.

3 In case of Valerian root used as powder, the total exposure to valepotriates should not exceed the maximum exposure with herbal tea. Alkylating and cytotoxic properties of valepotriates are not relevant for finished products. This is because valepotriates decompose rapidly and only traces of valepotriates or their degradation products (in part, baldrinals) are found.