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 HOP STROBILE

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Draft proposal for a core-data for Hop strobile

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

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[2]

Composition described in bibliographic data provided by the ESCOP monograph:
Hop strobile
Liquid extract, ethanolic 45 % (1:1)
Tincture, ethanolic 60 % (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

None accepted on the basis of bibliographic data provided by the ESCOP monograph.[3]

4.2. Posology and method of administration

Dosage described in bibliographic data provided by the ESCOP monograph:
For oral use.

Adults, elderly and children over 12 years of age
Drug as infusion: 0.5 g 2-4 times daily
Liquid extract, ethanolic 45 % (1:1), 0.5-2 ml once daily
Tincture, ethanolic 60 % (1:5), 1-2 ml once 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

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[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

[3] Decision by majority

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

None known

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

The alleged sedative effects of preparations of hop strobile such as tea infusions have long been recognised empirically but cannot be attributed with certainty to any known constituents. Hop preparations are mostly combined with other active substances. The contribution of hop to the efficacy in these preparations cannot be extracted from the published data. Indication could not be accepted because the uses cannot be made plausible by supportive pharmacological data.

5.2. Pharmacokinetic properties

No pharmacokinetic data available.

5.3. Preclinical safety data

Reports of oestrogenic activity in hop strobile have been inconclusive.