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

London, 17 December 2003
EMEA/HMPWP/1418/02

WORKING PARTY ON HERBAL MEDICINAL PRODUCTS (HMPWP)

FINAL PROPOSAL FOR A CORE-DATA FOR PEPPERMINT LEAF

DISCUSSION IN THE HMPWP	March, July & November 2002
TRANSMISSION TO CPMP	December 2002
RELEASE FOR CONSULTATION	December 2002
DEADLINE FOR COMMENTS	February 2003
REDISCUSSION IN THE HMPWP	November 2003
PUBLICATION OF FINAL PROPOSAL	December 2003

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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 7051
E-mail: mail@emea.eu.int http://www.emea.eu.int
©EMEA 2003 Reproduction and/or distribution of this document is authorised for non commercial purposes only provided the EMEA is acknowledged

Proposal for a Core-data on Peppermint leaf

The Working Party on Herbal Medicinal Products proposes the following core-data for *Menthae x piperitae folium*.

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

(i) Herbal drug

Whole or cut dried leaf of *Mentha x piperitae*[1] L.

(ii) Herbal drug preparation to be specified for the individual product

a) Infusion (water; 1:50 to 1:100)

b) Tinctures, liquid extracts (1:5; 45 % V/V ethanol)

for oral use

3. PHARMACEUTICAL FORM

Pharmaceutical form to be labelled according to the standard terms published by the European Pharmacopoeia.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications[2]

Herbal medicinal product for the symptomatic relief of minor digestive disorders.

4.2. Posology and method of administration

Daily dose for adults, elderly, adolescents (over 12 years of age):

Infusion: 1.5-3 g of the drug to 150 ml water, three times daily.

Tinctures, liquid extracts (1:5, 45 % V/V ethanol), 2-3 ml, three times daily.

Method of administration

Oral use

Duration of use

No restriction, but see 4.4 Special warnings and precautions for use.

[1] The herbal drug complies with the European Pharmacopoeia.
[2] Decision by majority

 ©EMEA 2003

4.3. Contraindications

Because there is no experience available, the use of this product is not recommended in children below the age of 2 years.

The product should not be used by patients with known hypersensitivity to Peppermint leaf preparations.

The product must not be used in patients with cholangitis, gallstones and any other biliary disorders.

4.4. Special warnings and precautions for use

Patients with gastroesophageal reflux (heartburn) should not take peppermint leaf preparations because heartburn may increase.

Because there is no experience available, use of this product is not recommended in children between the age of 2 and 12 years.

If symptoms persist or worsen after two weeks, a physician should be consulted.

4.5. Interaction with other medicaments and other form of interaction

None reported.

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 use (short term use).

4.9. Overdose

None reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

 ©EMEA 2003

Pharmacotherapeutic group: ATC code: A02D (Antiflatulents)

The pharmacological actions of Peppermint leaf are largely, but not exclusively, due to the presence of the essential oil; other components such as flavonoids appear to play a role as well (level IV)[3].

In vitro studies

Alcoholic extracts of Peppermint leaf have antispasmodic effects on the isolated guinea pig ileum. The effect obtained with 10.0 ml/litre extract (1:3.5, ethanol 30% m/m) corresponded to that of 0.13 mg atropine (effective dose of atropine in the treatment of abdominal spasms: 0.5 - 1.0 mg). Flavonoids isolated from Peppermint leaf and dissolved in water, so that 1 ml corresponded to approximately 0.5 g of dried leaf, inhibited muscular contractions of the guinea pig ileum induced by barium chloride.

In vivo studies

In experiments with cannulated dogs Peppermint tea (0.4 g/kg body weight) increased the secretion of bile. Flavonoids, as well as the essential oil, contribute to this action. An aqueous extract of Peppermint leaf (50 g of dried leaf infused for 10 min in 500 ml hot water, then spray-dried) administered orally showed a weak sedative action in several tests: hexobarbital-induced sleep, exploratory behaviour, spontaneous motility and motor coordination. The same Peppermint leaf extract, administered in the same two doses, showed a weak diuretic effect in mice.

5.2. Pharmacokinetic properties

Menthol and other terpene constituents of peppermint oil are rapidly absorbed and to some extent excreted in the form of glucuronide.

5.3. Preclinical safety data

Toxicity tests in animals have not given cause for concern within the recommended dosage range.

6. DATE OF COMPILATION

4 November 2003

[3] Points to consider on the evidence of safety and efficacy required for well-established herbal medicinal products in bibliographic applications (EMEA/HMPWP/23/99)

 ©EMEA 2003