European Medicines Agency
Evaluation of Medicines for Human Use

London, 4 September 2008
Doc. Ref. EMEA/HMPC/193909/2007

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

COMMUNITY HERBAL MONOGRAPH ON *MENTHA X PIPERITA* L., FOLIUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2007 July 2007
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	5 July 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 October 2007
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2008 May 2008
ADOPTION BY HMPC	4 September

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Mentha x piperita* L.; Menthae piperitae folium; peppermint leaf

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COMMUNITY HERBAL MONOGRAPH ON *MENTHA X PIPERITA* L., FOLIUM

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended i) Herbal substance: *Mentha x piperita* L., folium (dried peppermint leaf) ii) Herbal preparations: A) Comminuted herbal substance for tea preparation B) Tincture (1:5; ethanol 45 % (v/v)) C) Tincture (1:5; ethanol 70 % (v/v))

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal substance for infusion or other herbal preparation in liquid or solid dosage forms for oral use The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The declaration of the active substance(s) for an individual finished product should be done in accordance with relevant herbal quality guidance.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for the symptomatic relief of digestive disorders such as dyspepsia and flatulence. The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2 Posology and method of administration

Well-established use	Traditional use
	Posology *Adults, elderly* Daily dose Herbal tea: 4.5 - 9 g of the herbal substance, divided in three single doses. Tincture: 6-9 ml, divided in three single doses. *Children between 4 and 12 years of age, adolescents between 12 and 16 years of age* Daily dose Herbal tea only: Children between 4 and 12 years of age: 3-5 g Adolescents between 12 and 16 years of age: 3-6 g To be divided in three single doses. The use in children under 4 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted (see section 4.4 'Special warnings and precautions for use'). **Method of administration** Oral use.

4.3 Contraindications

Well-established use	Traditional use
	Hypersensitivity to peppermint leaf preparations or to menthol.

4.4 Special warnings and precautions for use

Well-established use	Traditional use
	Patients with gastro-oesophageal reflux (heartburn) should avoid peppermint leaf preparations, because heartburn may increase. Patients with gallstones and any other biliary disorders should be cautious using peppermint leaf preparations. The use in children under 4 years of age is not recommended as there is no experience available. If symptoms worsen during the use of the medicinal product, a doctor or a qualified health practitioner should be consulted. For tinctures containing ethanol the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5 Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6 Pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7 Effects on the ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Well-established use	Traditional use
	The gastro-oesophageal reflux may worsen and heartburn may increase. See also section 4.4 Special warnings and precautions of use.

4.9 Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

4 September 2008