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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
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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 COMPOSITION¹

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

3. PHARMACEUTICAL FORM

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

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

<u>Well-established use</u>	<u>Traditional use</u> 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.
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4.2 Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adults, elderly</i> 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. <i>Children between 4 and 12 years of age, adolescents between 12 and 16 years of age</i> Daily dose Herbal tea only: Children between 4 and 12 years of age 3-5 g age Adolescents between 12 and 16 3-6 g years of age 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.
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4.3 Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to peppermint leaf preparations or to menthol.
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4.4 Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> 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.
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4.5 Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> None reported.
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4.6 Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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4.7 Effects on the ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No studies on the effect on the ability to drive and use machines have been performed.
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4.8 Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> The gastro-oesophageal reflux may worsen and heartburn may increase. See also section 4.4 Special warnings and precautions of use.
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4.9 Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.3 Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u> 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.
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6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u> Not applicable.
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7. DATE OF COMPILATION/LAST REVISION

4 September 2008