EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2017
EMA/HMPC/572705/2014, *Corr.* [1]
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Mentha x piperita* L., folium

Draft

Initial assessment	
Discussion in Working Party on Community monographs and Community list (MLWP)	May 2007 July 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	05 July 2007
End of consultation (deadline for comments)	15 October 2007
Re-discussion in MLWP	March 2008 May 2008
Adoption by HMPC Monograph (EMA/HMPC/193909/2007) Assessment Report (EMA/HMPC/193910/2007) List of References (EMA/HMPC/262645/2007) Overview of comments (EMA/HMPC/101815/2008)	04 September 2008
First systematic review	
Discussion in Working Party on European Union monographs and list (MLWP)	September 2014 January 2015 March 2015 April 2016 May/June 2016 September 2016
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 January 2017
Start of public consultation	
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	31 May 2017

[1] End of consultation date corrected in table on page 1.

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Mentha x piperita* L., folium, Menthae piperitae folium, peppermint leaf

BG (bulgarski): Лютива мента, лист CS (čeština): list máty peprné DA (dansk): pebermynteblad DE (Deutsch): Pfefferminzblätter EL (elliniká): μίνθης πιπερώδους αιθέριο έλαιο EN (English): peppermint leaf ES (español): menta piperita, hoja de ET (eesti keel): piparmündileht FI (suomi): piparminttu, lehti FR (français): menthe poivrée (feuille de) HR (hrvatski): list paprene metvice HU (magyar): borsosmentalevél IT (italiano): Menta piperita foglia	LT (lietuvių kalba): Pipirmėčių lapai LV (latviešu valoda): Piparmētras lapas MT (Malti): werqa tal-menta NL (Nederlands): Pepermuntblad PL (polski): Liść mięty pieprzowej PT (português): hortelã-pimenta, folha RO (română): frunză de izmă bună; frunză de mentă SK (slovenčina): list mäty piepornej SL (slovenščina): list poprove mete SV (svenska): pepparmynta, blad IS (íslenska): NO (norsk): peppermynteblad

European Union 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[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC i) Herbal substance *Mentha x piperita* L., folium (dried peppermint leaf) ii) Herbal preparations a) Comminuted herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V)

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance and comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid 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 in accordance with relevant herbal quality guidance.
[3] The material complies with the Ph. Eur. Monograph (ref.: 0406)

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 the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[4]

Well-established use	Traditional use
	Posology *Children 4 - 11 years of age* Herbal tea: 1.0 to 1.5 g of the herbal substance or the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 3 times daily Daily dose: 3-4.5 g *Adolescents* Herbal tea: 1.0 to 2.0 g of the herbal substance or the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 3 times daily Daily dose: 3-6 g *Adults, elderly* Single dose: Herbal tea: 1.5 to 3.0 g of the of the herbal substance or the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 3 times daily Daily dose: 4.5-9 g Tincture b) and c): 2.0-3.0 ml, 3 times daily Daily dose: 6-9 ml. The use in children under 4 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').

[4] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	Duration of use If the symptoms persist longer 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 gastroesophageal 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 due to a lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For tinctures and extracts 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. Fertility, 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. No fertility data available.

4.7. Effects on 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 gastroesophageal reflux may worsen and heartburn may increase. The frequency is not known. See also section 4.4 'Special warnings and precautions of use'. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

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.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

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

31 January 2017