



15 January 2020
EMA/HMPC/572705/2014
Committee on Herbal Medicinal Products (HMPC)

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

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	May 2007 July 2007
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	5 July 2007
End of consultation	10 October 2007
Re-discussion in MLWP	March 2008 May 2008
Adoption by HMPC Monograph (EMA/HMPC/349466/2006) AR (EMA/HMPC/193910/2007) List of references (EMA/HMPC/262645/2007) Overview of comments received during the public consultation (EMA/HMPC/101815/2008) HMPC Opinion (EMA/HMPC/189852/2008)	4 September 2008
First systematic review	
Discussion in MLWP	September 2014 January 2015 March 2015 April 2016 May/June 2016 September 2016
Adopted by HMPC for release for consultation	31 January 2017
Start of public consultation	31 May 2017
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Re-discussion in HMPC/MLWP	June 2017 March 2018 January 2019 May 2019 January 2020
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Mentha x piperita</i> L., folium; <i>Menthae piperitae</i> folium; peppermint leaf
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<p>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</p> <p>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</p>	<p>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 máty piepornej SL (slovenščina): list poprove mete SV (svenska): pepparmyntolja IS (íslenska): NO (norsk): peppermyntheblad</p>
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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 composition¹

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC i) Herbal substance <i>Mentha x piperita</i> L., folium (dried peppermint leaf) ii) Herbal preparations A. Comminuted herbal substance 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 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.

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

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

Well-established use	Traditional use
	product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration²

Well-established use	Traditional use
	<p>Posology</p> <p><i>Children 4-11 years of age and adolescents</i></p> <p>Herbal tea: 1.0-2.0 g of the herbal substance or the comminuted herbal substance in 100-150 ml of boiling water as a herbal infusion 3 times daily</p> <p><i>Adults, elderly</i></p> <p>Single dose</p> <p>Herbal tea: 1.5-3.0 g of the herbal substance or the comminuted herbal substance in 100-150 ml of boiling water as a herbal infusion 3 times daily</p> <p>Preparations B), C) Tincture: 2.0-3.0 ml, 3 times daily.</p> <p>The use is not recommended in children under 4 years of age (see section 4.4 Special warnings and precautions for use).</p> <p>Duration of use</p> <p>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).</p> <p>Method of administration</p> <p>Oral use</p>

4.3. Contraindications

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

² 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).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Patients with gastroesophageal reflux (heartburn) should avoid peppermint leaf preparations, because heartburn may increase.</p> <p>Patients with gallstones and any other biliary disorders should be cautious using peppermint leaf preparations.</p> <p>The use in children under 4 years of age is not recommended due to a lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>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.</p>

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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

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

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

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

15 January 2020