



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 January 2020
EMA/HMPC/679997/2013
Committee on Herbal Medicinal Products (HMPC)

European Union list entry on *Mentha x piperita* L., aetheroleum

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	January 2007 March 2007 May 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	8 May 2007
End of consultation (deadline for comments)	15 August 2007
Re-discussion in MLWP	October 2007
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First revision	
Discussion in MLWP	September 2013 November 2013 January 2014 March 2014 January 2015 March 2015 April 2016 May/June 2016 September 2016 January 2017 March 2017 May 2017 July 2017 January 2018 March 2018 January 2019
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Keywords	Herbal medicinal products; HMPC; European Union list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Mentha x piperita</i> L., aetheroleum; <i>Menthae piperitae</i> aetheroleum; peppermint oil
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Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Mentha x piperita* L., aetheroleum

Scientific name of the plant	
<i>Mentha x piperita</i> L.	
Botanical family	
Lamiaceae (Labiatae)	
Herbal substance	
Not applicable	
Common name of <i>Mentha x piperita</i> L., aetheroleum in all EU official languages	
BG (bългарски): Лютива мента, масло CS (čeština): silice máty peprné DA (dansk): Pebermynteolie DE (Deutsch): Pfefferminzöl EL (elliniká): αιθέριο έλαιο μίνθης EN (English): peppermint oil ES (español): menta piperita, aceite esencial de ET (eesti keel): piparmündiõli FI (suomi): piparminttuöljy FR (français): menthe poivrée (huile essentielle de) HR (hrvatski): eterično ulje paprene metvice HU (magyar): borsosmentaolaj IT (italiano): Menta piperita essenza	LT (lietuvių kalba): Pipirmėčių eterinis aliejus LV (latviešu valoda): Piparmētras ēteriskā eļļa MT (malti): żejt tal-menta NL (nederlands): Pepermuntolie PL (polski): Olejek eteryczny mietowy PT (português): óleo essencial de hortelã-pimenta RO (română): ulei volatil de izmă bună; ulei volatil de mentă SK (slovenčina): silica máty piepornej SL (slovenščina): eterično olje poprove mete SV (svenska): pepparmyntolja IS (íslenska): NO (norsk): peppermynnteolje
Herbal preparation	
Peppermint oil: essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant	
European Pharmacopoeia monograph reference	
Peppermint oil – Menthae piperitae aetheroleum (0405)	
Indications	
Indication 1) Traditional herbal medicinal product used for the relief of symptoms in coughs and colds.	
Indication 2) Traditional herbal medicinal product used for the symptomatic relief of localised muscle pain.	
Indication 3) Traditional herbal medicinal product used for the symptomatic relief of localised pruritic conditions	

in intact skin. The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.
Type of tradition
European
Specified strength
Indications 1), 2) and 3) Single dose <u>Cutaneous and transdermal use</u> <i>Children 4 to 11 years of age</i> Semi-solid preparations 2-10% Hydroethanolic preparations 2-4% <i>Adolescents</i> Semi-solid preparations 5-15% Hydroethanolic preparations 3-6% <i>Adults, elderly</i> Semi-solid and oily preparations 5-20% In Hydroethanolic preparations 5-10% Indication 1) <i>Adolescents, adults and elderly</i> In nasal ointments 1-5% essential oil.
Specified posology
Up to three times daily Indication 1) Apply a thin layer on the chest or on the back or around the nostrils. Indications 2) and 3) Apply a thin layer on the affected area. The amount of the preparation of the daily dose must not exceed the limit of pulegone and menthofuran (see Pharmaceutical particulars). The use in children under 2 years of age is contraindicated (see Contraindications). The use is not recommended in children 2-3 years of age (see Special warnings and precautions for use). The nasal application is not recommended in children between 2 and 11 years of age (see Special warnings and precautions for use).

Route of administration
Cutaneous and transdermal.
Duration of use or any restrictions on the duration of use
Indications 2) and 3) It is not recommended to use the medicinal product continuously for more than 2 weeks. Indications 1), 2) and 3) 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.
Any other information necessary for the safe use
Contraindications Children under 2 years of age, because menthol can induce reflex apnoea and laryngospasm. Children with history of seizures (febrile or not). Hypersensitivity to peppermint oil or menthol. Special warnings and precautions for use Eye contact with unwashed hands after the application of peppermint oil may potentially cause irritation. Peppermint oil should not be applied on broken or irritated skin. The use in children between 2 to 3 years of age has not been established due to lack of adequate data. The nasal application in children from 2 to 11 years of age has not been established due to lack of adequate data. Other medicinal products containing peppermint oil shall be avoided during the use of this medicinal product. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Interactions with other medicinal products and other forms of interaction None reported Fertility, Pregnancy and lactation In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available. Effects on ability to drive and use machines No studies on the effect on the ability to drive and use machines have been performed. Undesirable effects Hypersensitivity reactions such as skin rash, contact dermatitis, and eye irritation have been reported. These reactions are most of the time mild and transient. The frequency is not known. Irritation of the skin and mucosa of the nose is possible, after local application. The frequency is not

known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars

A limit of pulegone and menthofuran corresponding to the exposure of 0.75 mg/kg bw per day for children, adolescents and adults should not be exceeded.

For more details see the "Public statement on the use of herbal medicinal products containing pulegone and menthofuran)" (EMA/HMPC/138386/2005 Rev. 1).

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience

Not applicable

Date of compilation/Last revision

15 January 2020