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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)**

**DRAFT**

**COMMUNITY LIST ENTRY ON  
*MENTHA x PIPERITA* L., AETHEROLEUM**

<b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	May 2008
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	8 May 2008
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS )</b>	15 September 2008
<b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	
<b>ADOPTION BY HMPC</b>	

Comments should be provided using this [template](#) to [hmpc.secretariat@emea.europa.eu](mailto:hmpc.secretariat@emea.europa.eu)  
Fax: +44 20 75 23 70 51

<b>KEYWORDS</b>	Herbal medicinal products; HMPC; Community 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.; Menthae piperitae aetheroleum; peppermint oil
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**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND  
COMBINATIONS THEREOF FOR USE IN  
TRADITIONAL HERBAL MEDICINAL PRODUCTS**

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COMBINATIONS THEREOF FOR USE IN  
TRADITIONAL HERBAL MEDICINAL PRODUCTS:**

*MENTHA x PIPERITA L., AETHEROLEUM*

<b>Scientific name of the plant</b>	
<i>Mentha x piperita L.</i>	
<b>Botanical family</b>	
Lamiaceae (Labiatae)	
<b>Herbal substance</b>	
Not applicable	
<b>Common name in all EU official languages of herbal substance</b>	
BG (bългарski):	IT (italiano):
CS (čeština):	LT (lietuvių kalba):
DA (dansk):	LV (latviešu valoda):
DE (Deutsch):	MT (malti):
EL (elliniká):	NL (nederlands):
EN (English):	PL (polski):
ES (español):	PT (português):
ET (eesti keel):	RO (română):
FI (suomi):	SK (slovenčina):
FR (français):	SL (slovenščina):
HU (magyar):	SV (svenska):
	<i>IS (íslenska):</i>
	<i>NO (norsk):</i>
<b>Herbal preparation(s)</b>	
Peppermint oil: essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant	
<b>European Pharmacopoeia monograph reference</b>	
Peppermint oil – <i>Menthae piperitae aetheroleum</i> (01/2008:0405)	
<b>Indication(s)</b>	
Herbal medicinal product traditionally used	
1. For the relief of symptoms in coughs and colds	
2. For the symptomatic relief of localised muscle pain	
3. For the symptomatic relief of localised pruritic conditions in intact skin	
The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.	

<b>Type of tradition</b>
European
<b>Specified strength</b>
<p>Indications 1, 2 and 3  Single dose  <i>Children between 4 to 10 years of age</i>  Semi-solid preparations 2 - 10%  Hydroethanolic preparations 2 - 4%</p> <p><i>Children between 10 to 12 years of age, adolescents between 12 to 16 years of age</i>  Semi-solid preparations 5 - 15%  Hydroethanolic preparations 3 - 6%</p> <p><i>Adolescents over 16 years of age, adults</i>  Semi-solid and oily preparations 5 - 20%  In aqueous-ethanol preparations 5 - 10%  In nasal ointments 1 - 5% essential oil.</p>
<b>Specified posology</b>
<p>Up to three times daily</p> <p>The use in children under 2 years of age is contraindicated (see Contraindications).  The use is not recommended in children between 2 to 4 years of age (see Special warnings and precautions for use).</p>
<b>Route of administration</b>
Cutaneous and transdermal.
<b>Duration of use or any restrictions on the duration of use</b>
<p>Indication 1</p> <p>Not to be used for more than 2 weeks.</p> <p>Indications 2 and 3</p> <p>It is not recommended to use the medicinal product continuously for more than 3 months.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>
<b>Any other information necessary for the safe use</b>
<b>Contraindications</b>
<p>Children under 2 years of age, because menthol can induce reflex apnoea and laryngospasm.</p> <p>Children with history of seizures (febrile or not).</p> <p>Hypersensitivity to peppermint oil or menthol.</p>

**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 is not recommended in children between 2 to 4 years of age, as there is no sufficient experience available.

**Interactions with other medicinal products and other forms of interaction**

None reported.

**Pregnancy and lactation**

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

**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 [If necessary]**

Not applicable.

**Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]**

Not applicable.

**Date of compilation/Last revision**

08 May 2008