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

**FINAL**

**COMMUNITY HERBAL MONOGRAPH ON *ARTEMISIA ABSINTHIUM* L., HERBA**

<b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	May 2008 July 2008 September 2008 November 2008
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	6 November 2008
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	15 March 2008
<b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	May 2009 July 2009
<b>ADOPTION BY HMPC</b>	16 July 2009

<b>KEYWORDS</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Artemisia absinthium</i> L.; Absinthii herba; wormwood herb
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BG (bългарски): Абсент CS (čeština): pelyňková nat' DA (dansk): Absint DE (Deutsch): Magenkraut, Wermutkraut EL (elliniká): Αψίνθιο ή Αρτεμισία EN (English): Wormwood herb ES (español): absintio, absenta, ajenjo ET (eesti keel): koirohi FI (suomi): FR (français): absinthe HU (magyar): Abszint	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): Assenzju NL (nederlands): alsem PL (polski): Ziele piolunu PT (português): absinto RO (română): Iarbă de pelin SK (slovenčina): Palinová vňat' SL (slovenščina): zel pravega pelina SV (svenska): Absinth IS (íslenska):
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Superseded

## COMMUNITY HERBAL MONOGRAPH ON *ARTEMISIA ABSINTHIUM* L., HERBA

### 1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1,2</sup>

<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>Artemisia absinthium</i> L., herba (wormwood herb)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none"><li>- Comminuted herbal substance</li><li>- Expressed juice from the fresh herb (1:0.5-0.9)</li><li>- Tincture (1:5, ethanol 70% v/v)</li></ul>

### 3. PHARMACEUTICAL FORM

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

<sup>1</sup> The material complies with the Eur. Ph. monograph (01/2008:1380corrected 6.0).

<sup>2</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>  a) Traditional herbal medicinal product used in temporary loss of appetite.  b) Traditional herbal medicinal product used in mild dyspeptic/gastrointestinal disorders.  The product is a traditional herbal medicinal product for use in specified indications 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>  <b>Posology</b>  <i>Adults, elderly</i>  <b>Indication a)</b> <b>Daily dose</b>  Herbal tea: 2-3 g of the comminuted herbal substance, divided in two to three single doses.  Expressed juice: 10 ml, divided in two single doses.  Tincture: equivalent to 2-3 g herbal substance, divided in two to three single doses.  To be taken 30 minutes before meals.  <b>Indication b)</b> <b>Daily dose</b>  Herbal tea: 2-3 g of the comminuted herbal substance, divided in two to three single doses.  Comminuted herbal substance in tablets: 2.28 g herbal substance, divided in three single doses.  Expressed juice: 10 ml, divided in two single doses.  Tincture: equivalent to 2-3 g herbal substance, divided in two to three single doses.  To be taken after meals.  For tea preparation, pour 150 ml of boiling water over 1 g of comminuted herbal substance. Steep for 10 minutes.
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	<p><b>Indications a) and b)</b></p> <p>The intake of thujone should not exceed 3.0 mg/day.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).</p> <p><b>Duration of use</b></p> <p><b>Indication a) and b)</b></p> <p>Not to be used for more than 2 weeks.</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> <p><b>Method of administration</b></p> <p>Oral use.</p>
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#### 4.3. Contraindications

<u>Well-established use</u>	<p><u>Traditional use</u></p> <p>Hypersensitivity to the active substance(s) and to other plants of the Asteraceae (Compositae) family.</p> <p>Obstruction of the bile duct, cholangitis or liver disease.</p>
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#### 4.4. Special warnings and precautions for use

<u>Well-established use</u>	<p><u>Traditional use</u></p> <p>Patients with gallstones and any other biliary disorders should consult a doctor before using Absinthii herba preparations.</p> <p>The intake of Absinthii herba preparations might influence the effect of medicinal products acting via GABA receptor, even if not seen clinically.</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>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.</p>
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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>  There are no or limited data from use during pregnancy and lactation.  The use should be avoided during pregnancy and lactation (see section 5.3 'Preclinical safety data').
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#### 4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u>  May impair ability to drive and use machines. Affected patients should not drive or operate machinery.
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#### 4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>  None known.  If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.
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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.

## 5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	<p>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.</p> <p>Thujone is reported to be neurotoxic and chemotypes with low content of thujone should be preferred.</p> <p>Tests on reproductive toxicity have been performed with a dry ethanolic extract of Absinthii herba administered orally to pregnant rats. Results showed reduced sites of implantations and a reduced rate of born pups. Thujone is known for its uterus stimulating activity.</p> <p>A daily intake of 3.0 mg/person is acceptable for a maximum duration of use of 2 weeks.</p> <p>Tests on genotoxicity, carcinogenicity and reproductive toxicity have not been performed with preparations of Absinthii herba covered by this monograph.</p>

## 6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

## 7. DATE OF COMPILATION/LAST REVISION

16 July 2009