



London, 6 November 2008
Doc. Ref. EMEA/HMPC/234463/2008 *Corr.*

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

DRAFT

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

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

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

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Artemisia absinthium</i> L.; Absinthii herba; wormwood herb
-----------------	---

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^{1,2}

<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">- Comminuted herbal substance- Expressed juice from the fresh herb (1:0.5-0.9)- Tincture (1:5, ethanol 70% V/V)

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Herbal preparations 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>

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

² 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.
-----------------------------	---

4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adults, Elderly</i> Indication a) Daily dose 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 min before meals Indication b) Daily dose 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
-----------------------------	--

	<p>Tincture: equivalent to 2-3 g herbal substance, divided in two to three single doses</p> <p>To be taken after meals</p> <p>To make a herbal tea, pour 150 ml of boiling water over 1 g of comminuted herbal substance. Steep for 10 minutes.</p> <p>Indications a) and b) The intake of thujone should not exceed 3 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>Duration of use</p> <p>Indications a) and b) Duration of use should be restricted to a maximum of 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>Method of administration</p> <p>Oral use.</p>
--	---

4.3. Contraindications

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

4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> Patients with gallstones and any other biliary disorders should consult a doctor before using Absinthii herba preparations. The use in children and adolescents is not recommended because data are not sufficient and medical advice should be sought. 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.
-----------------------------	---

4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> None reported. The intake of Absinthii herba preparations might influence the effect of medicinal products acting via GABA receptor (e.g. barbiturates, benzodiazepines), even if not seen clinically. Therefore the concomitant use with such medicinal products is not recommended.
-----------------------------	--

4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
-----------------------------	--

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.
-----------------------------	--

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.
-----------------------------	--

4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
-----------------------------	--

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.
-----------------------------	--

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> 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. Thujone is reported to be neurotoxic and chemotypes with low content of thujone should be preferred. A daily intake of 3 mg/person is acceptable for a maximum duration of use of 2 weeks. Tests on genotoxicity, carcinogenicity and reproductive toxicity have not been performed with preparations of Absinthii herba.
-----------------------------	---

6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u> The content of thujone must be shown for every batch.
-----------------------------	---

7. DATE OF COMPILATION/LAST REVISION

6 November 2008