European Medicines Agency
Evaluation of Medicines for Human Use

London, 16 July 2009
Doc. Ref.: EMEA/HMPC/234463/2008

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

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)	15 March 2008
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2009 July 2009
ADOPTION BY HMPC	16 July 2009

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Artemisia absinthium* L.; Absinthii herba; wormwood herb

BG (bălgarski): Абсент
CS (čeština): pelyňková nať
DA (dansk): Absint
DE (Deutsch): Magenkraut, Wermutkraut
EL (elliniká): Αψίνθιο η Αρτεμισία
EN (English): Wormwood herb
ES (espanol): absintio, absenta, ajenjo
ET (eesti keel): koirohi
FI (suomi):
FR (français): absinthe
HU (magyar): Abszint
IT (italiano): assenzio
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 vňať
SL (slovenščina): zel pravega pelina
SV (svenska): Absinth
IS (íslenska):
NO (norsk): Malurt

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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]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Artemisia absinthium* L., herba (wormwood herb) i) Herbal substance Not applicable. ii) Herbal preparations - Comminuted herbal substance - Expressed juice from the fresh herb (1:0.5-0.9) - Tincture (1:5, ethanol 70% v/v)

3. PHARMACEUTICAL FORM

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

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

Well-established use	Traditional use
	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

Well-established use	Traditional use
	Posology *Adults, elderly* 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 minutes 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. 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.

	Indications a) and b) The intake of thujone should not exceed 3.0 mg/day. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication a) and b) Not to be used for more than 2 weeks. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Patients with gallstones and any other biliary disorders should consult a doctor before using Absinthii herba preparations. The intake of Absinthii herba preparations might influence the effect of medicinal products acting via GABA receptor, even if not seen clinically. The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. 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

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	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').

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

4.8. Undesirable effects

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

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 as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	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. 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. A daily intake of 3.0 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 covered by this monograph.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

16 July 2009