4 March 2020
EMA/HMPC/751490/2016 Corr. [1]
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Artemisia absinthium* L., herba

Final

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	May 2008 July 2008 September 2008 November 2008
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	November 2008
End of consultation (deadline for comments[2]).	March 2009
Re-discussion in MLWP	May 2009 Jul 2009
Adoption by HMPC Monograph (EMEA/HMPC/234463/2008) AR (EMEA/HMPC/234444/2008) List of references (EMEA/HMPC/234497/2008) HMPC Opinion (EMEA/HMPC/375221/2009EN)	July 2009
First systematic review	
Discussion in Working Party on European Union monographs and list (MLWP)	November 2016 March 2017
Adoption by HMPC	May 2017

[1] The monograph has been corrected in section 4.7. For further information see the Addendum to the assessment report on *Artemisia absinthium* L., herba (EMA/HMPC/13144/2020).
[2] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2020. Reproduction is authorised provided the source is acknowledged.

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Artemisia absinthium* L., herba; Absinthii herba; wormwood

BG (bulgarski): Горчив пелин, стрък CS (čeština): pelyňková nať DA (dansk): Malurt DE (Deutsch): Wermutkraut EL (elliniká): πόα αρτεμισίας - πόα αψινθίου EN (English): wormwood ES (español): ajenjo, sumidad florida de, absenta ET (eesti keel): koirohuürt FI (suomi): koiruoro (mali) FR (français): absinthe HR (hrvatski): pelinova zelen HU (magyar): fehér üröm leveles vagy virágos hajtás IT (italiano): Assenzio parti aeree	LT (lietuvių kalba): Karčiųjų kiečių žolė LV (latviešu valoda): Vērmeles laksti MT (Malti): assenzju NL (Nederlands): absintalsem PL (polski): ziele piołunu PT (português): absinto RO (română): iarbă de pelin SK (slovenčina): vňať paliny SL (slovenščina): zel pravega pelina SV (svenska): malört, ört IS (íslenska): NO (norsk): malurt

European Union 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[3,4]

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

3. Pharmaceutical form

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

[3] The declaration of active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance
[4] The material complies with the Ph. Eur. Monograph (ref.: 1380)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product for temporary loss of appetite. Indication 2) Traditional herbal medicinal product for 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[5]

Well-established use	Traditional use
	Posology Indication 1) *Adults and elderly* a) Single dose herbal tea 1-1.5 g comminuted herbal substance in 150 ml of boiling water as an infusion Single dose: 1-1.5 g Daily dose: 2-3 g c) Expressed juice Single dose: 5 ml Daily dose: 10 ml d) Tincture Single dose: 1 g Daily dose: 3 g Indication 2) *Adults and elderly* a) Single dose herbal tea 1-1.5 g comminuted herbal substance in 150 ml of boiling water as

[5] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	an infusion Single dose: 1-1.5 g Daily dose: 2-3 g b) Powdered herbal substance Single dose: 0.76 g Daily dose: 2.28 g c) Expressed juice Single dose: 5 ml Daily dose: 10 ml d) Tincture Single dose: 1 g Daily dose: 3 g Indications 1) and 2) 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** 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. **Method of administration** Oral use Indication 1) To be taken 30 minutes before meals. Indication 2) To be taken after meals.

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 (see section 4.3) should consult a doctor before using Absinthii herba preparations. The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. 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. Fertility, pregnancy and lactation

Well-established use	Traditional use
	There are no or limited data from use during pregnancy and lactation. The use is not recommended during pregnancy and lactation. No fertility data available.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

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.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

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

Well-established use	Traditional use
	Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed with the preparations of Absinthii herba covered by this monograph.

6. Pharmaceutical particulars

Well-established use	Traditional use
	The amount of thujone has to be specified in the given product. The daily exposure has to be below 6.0 mg. For more details see the “Public statement on the use of herbal medicinal products containing thujone)” (EMA/HMPC/732886/2010).

7. Date of compilation / last revision

30 May 2017