



5 April 2016
EMA/HMPC/41108/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Helichrysum arenarium* (L.) Moench, flos

Final

Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2014 January 2015 May 2015 July 2015
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	29 September 2015
Start of public consultation	15 October 2015
End of consultation (deadline for comments ¹).	15 January 2016
Rediscussion in MLWP	February 2016
Adoption by HMPC	5 April 2016

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Helichrysum arenarium</i> (L.) Moench, flos; Helichrysi flos; sandy everlasting
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BG (bulgarski): Жълт смил, цвят CS (čeština): květ smilu písečného DA (dansk): Evighedsblomst DE (Deutsch): Ruhrkrautblüten EL (elliniká): Άνθος ελιχρύσου EN (English): sandy everlasting ES (español): Perpetuas amarillas, flor ET (eesti keel): kääkullaõis FI (suomi): hietakikukka, kukka FR (français): Immortelle (fleur d') HR (hrvatski): cvijet smilja HU (magyar): Homoki szalma gyopárvirág IT (italiano): n/a	LT (lietuvių kalba): Šlamučių žiedai LV (latviešu valoda): Dzeltēnās kaķpēdiņas ziedi MT (Malti): fjuri tas-Sempreviva safra NL (Nederlands): Kerrieplant, bloem PL (polski): Kwiat kocanek PT (português): Perpétuas-das-areias RO (română): flori de paie SK (slovenčina): Kvet slamihy SL (slovenščina): zel peščenega smilja SV (svenska): Hedblomster, blomma <i>IS (íslenska):</i> <i>NO (norsk):</i> Sandstråblom
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¹ 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'.



European Union herbal monograph on *Helichrysum arenarium* (L.) Moench, flos

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{2,3}

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Helichrysum arenarium</i> (L.) Moench, flos (sandy everlasting) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used in digestive disorders with a feeling of fullness and bloating. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

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

³ The herbal substance complies with the monograph *Helichrysi flos* in Farmakopea Polska X, 2014, Vol. II, p. 4039

4.2. Posology and method of administration⁴

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Single dose</p> <p>1.5 g of comminuted herbal substance in 150-250 ml of water as a decoction for 10 minutes 2 - 3 times daily.</p> <p>or</p> <p>3 g of comminuted herbal substance, in 150-200 ml of boiling water, as an infusion, 1 - 3 times daily.</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>If the symptoms persist longer than two weeks 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> <p>To be taken 15-30 minutes before meal or when the symptoms appear.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to plants of the Asteraceae family (Compositae).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>Due to the possible stimulation of bile secretion</p>

⁴ 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
	<p>Helichrysi flos is not recommended in case of obstruction of the bile duct, cholangitis, liver disease and gallstones.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

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
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

5 April 2016