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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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BG (bulgarski): Жълт смил, цвят	LT (lietuvių kalba): Šlamučių žiedai
CS (čeština): květ smilu písečného	LV (latviešu valoda): Dzeltenās kaķpēdiņas ziedi
DA (dansk): Evighedsblomst	MT (Malti): fjuri tas-Sempreviva safra
DE (Deutsch): Ruhrkrautblüten	NL (Nederlands): Kerrieplant, bloem
EL (elliniká): Άνθος ελιχρύσου	PL (polski): Kwiat kocanek
EN (English): Sandy everlasting	PT (português): Perpétuas-das-areias
ES (español): Perpetua, flor de	RO (română):
ET (eesti keel): käokullaõis	SK (slovenčina): Kvet slamihy
FI (suomi): hietaolkikukka, kukka	SL (slovenščina): zel peščenega smilja
FR (français): Immortelle (fleur d')	SV (svenska): Hedblomster, blomma
HR (hrvatski): cvijet smilja	*IS (íslenska)*:
HU (magyar): Homoki szalma gyopárvirág	*NO (norsk):* Sandstråblom
IT (italiano):	

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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[1,2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Helichrysum arenarium* (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 specified indication exclusively based upon long-standing use.

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] The herbal substance complies with the monograph Helichrysi flos in Farmakopea Polska X, 2014, Vol. II, p. 4039

4.2. Posology and method of administration[3]

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

4.3. Contraindications

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

4.4. Special warnings and precautions for use

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

[3] 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
	Helichrysi flos is not recommended in case of obstruction of the bile duct, cholangitis, liver disease and gallstones. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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
	No fertility data available. 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

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 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. Adequate 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

29 September 2015