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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Centaurium erythraea* Rafn. s.l., herba

Final

Initial assessment	
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Adoption by HMPC Monograph (EMEA/HMPC/105536/2008) Assessment Report (EMEA/HMPC/105535/2008) List of references (EMEA/HMPC/105618/2008) Overview of comments (EMEA/HMPC/664610/2008)	12 March 2009
First revision	
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30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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BG (bulgarski): Червен кантарион, стрък	IT (italiano): Centaurea minore parti aeree fiorite
CS (čeština): zeměžlučová nať	LT (lietuvių kalba): Širdažolių žolė
DA (dansk): Tusindgylden	LV (latviešu valoda): Augstiņa laksti
DE (Deutsch): Tausendgüldenkraut	MT (Malti): Ċentawrija
EL (elliniká): πόα κενταυρίου	NL (Nederlands): Duizendguldenkruid
EN (English): Centaury	PL (polski): Ziele centurii
ES (español): Centaura menor, sumidad de	PT (português): Centáurea-menor
ET (eesti keel): maasapiürt	RO (română): iarbă de ţintaură
FI (suomi): rohtosappi (rohtorantasappi)	SK (slovenčina): Vňať zemežlče
FR (français): Petite centaurée (parties aériennes fleuries de)	SL (slovenščina): zel navadne tavžentrože
	SV (svenska): Tusengyllenört, ört
HR (hrvatski): kičicina zelen	IS (íslenska):
HU (magyar): kis ezerjófű virágos hajtás	NO (norsk): Skjermgyllen

European Union herbal monograph on *Centaurium erythraea* Rafn. s.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 *Centaurium erythraea* Rafn. s.l. including *C. majus* (H. et L.) Zeltner and *C. suffruticosum* (Griseb.) Ronn. (syn.: *Erythraea centaurium* Persoon; *C. umbellatum* Gilibert; *C. minus* Gars.), herba (Centaury) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V d) Tincture (DER 1:5), extraction solvent ethanol 70% V/V e) Soft extract (DER 1:10), extraction solvent water

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.

1 The material complies with the Ph. Eur. monograph (ref.: 1301).
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
	Traditional herbal medicinal product used in mild dyspeptic/gastrointestinal disorders and in temporary loss of appetite. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adults and elderly* a) Herbal tea: 1-4 g of the comminuted herbal substance in 200 ml of boiling water as a herbal infusion, up to 4 times daily b) Powdered herbal substance: single dose 0.25-2 g, up to 3 times daily c) Liquid extract: single dose: 2-4 ml, up to 3 times daily d) Tincture: single dose: 1.5-5 g, up to 3 times daily e) Soft extract: single dose 0.2 g; daily dose: 1-2 g 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.

[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).

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s). Peptic ulcer.

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. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For tinctures and extracts 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
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. 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
	Stomach disturbances and nausea have 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

24 November 2015