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FINAL

COMMUNITY HERBAL MONOGRAPH ON *CENTAURIUM ERYTHRAEA* RAFN, HERBA

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2008 May 2008 July 2008
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COMMUNITY HERBAL MONOGRAPH ON *CENTAURIUM ERYTHRAEA* RAFN, HERBA

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Centaurium erythraea</i> Rafn s. l. including <i>C. majus</i> (H. et L.) Zeltner and <i>C. suffruticosum</i> (Griseb.) Ronn. (syn.: <i>Erythraea centaurium</i> Persoon; <i>C. umbellatum</i> Gilibert; <i>C. minus</i> Gars.), herba (centaury herb)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations</p> <p>A) Comminuted herbal substance</p> <p>B) Powdered herbal substance</p> <p>C) Liquid extract (1:1; ethanol 25% v/v)</p> <p>D) Tincture (1:5; ethanol 70% v/v)</p> <p>E) Soft extract (1:10; water)</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Comminuted herbal substance as herbal tea or other herbal preparations in liquid or solid dosage forms for oral use.</p>

¹ The material complies with the Ph. Eur. monograph (ref. 01/2005:0865).

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

<u>Well-established use</u>	<u>Traditional use</u> Traditional herbal medicinal product used in mild dyspeptic/gastrointestinal disorders, and/or in temporary loss of appetite. The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use and experience.
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4.2 Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adults and elderly</i> ii) Herbal preparations A) Comminuted herbal substance for tea preparation: single dose 1-4 g, 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 precaution 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.
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>
	Hypersensitivity to the active substance. Active peptic ulcer.

4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
	The use in children and adolescents under 18 years of age is not recommended 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

<u>Well-established use</u>	<u>Traditional use</u>
	None reported.

4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
	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

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

4.8. Undesirable effects

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

4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u>
	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	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 with preparations of Centaurii herba have not been performed.

6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

12 March 2009