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FINAL

COMMUNITY HERBAL MONOGRAPH ON *GENTIANA LUTEA* L., RADIX

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

COMMUNITY HERBAL MONOGRAPH ON *GENTIANA LUTEA* L., RADIX

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 *Gentiana lutea* L., radix (gentian root) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Dry extract (DER 4.5-5.5:1), extraction solvent ethanol 53% v/v c) Tincture (Ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% v/v d) Liquid extract (DER 1:1), extraction solvent ethanol 45% v/v

3. PHARMACEUTICAL FORM

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

[1] The material complies with the Eur. Ph. monograph (ref.: 01/2008:0392).
[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/or in temporary loss of appetite. 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

Well-established use	Traditional use
	Posology *Adults, elderly* Average daily dose a) Comminuted herbal substance for tea preparation: 1-2 g, 3-4 times daily b) Dry extract: 2 capsules of 120 mg dry extract each, 2-3 times daily c) Tincture: 1 ml, 1-3 times daily d) Liquid extract: 1 g, 2-4 times daily For the indication "loss of appetite", in the literature, it is described that the liquid preparations a), c) and d) are supposed to be taken ½ hour before meal. Correspondingly, the solid dosage form b) is supposed to be taken 1 hour before meal due to the additional mechanism of disintegration of the solid form. 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.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. 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 is not recommended due to lack of adequate data. For tinctures and liquid 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. 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 (see section 5.3 'Preclinical safety data').

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
	Gastrointestinal disorders have been observed. The frequency was uncommon. In rare cases, tachycardia and pruritus have been reported. Headache may occur. The frequency is not known. If other adverse reactions not mentioned above 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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. For some xanthones which are among the constituents of *Gentiana lutea*, positive results

	were found in the AMES test (pre-incubation method). Assessment of preclinical safety requires further studies towards these effects.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use Not applicable.

7. DATE OF COMPILATION/LAST REVISION

12 November 2009