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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Gentiana lutea* L., radix

Draft

Discussion in Working Party on European Union monographs and European Union list (MLWP)	January 2009 March 2009
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Re-discussion in MLWP	September 2009 November 2009
Adoption by HMPC Monograph (EMEA/HMPC/578324/2008) AR (EMEA/HMPC/ 578322/2008) List of references (EMEA/HMPC/ 578323/2008) Overview of comments received during the public consultation (EMEA/HMPC/ 573967/2009) HMPC Opinion (EMEA/HMPC/ 678928/2009)	November 2009
First systematic review	
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BG (bulgarski): Тинтява, корен	LT (lietuvių kalba): Gencijonų šaknys
CS (čeština): hořcový kořen	LV (latviešu valoda): Genciānas saknes
DA (dansk): Ensianrod	MT (Malti): għerq tal-ġenzjana
DE (Deutsch): Enzianwurzel	NL (Nederlands): Gele Gentiaan
EL (elliniká): ρίζα γεντιανής	PL (polski): Korzeń goryczki
EN (English): gentian root	PT (português): genciana, raiz
ES (español): genciana, raíz de	RO (română): rădăcină de ghințură/rădăcină de gențiană
ET (eesti keel): emajuurejuur	SK (slovenčina): koreň horca
FI (suomi): keltakatkeron, juuri	SL (slovenščina): korenina rumenega svišča
FR (français): gentiane (racine de)	SV (svenska): gentiana, rot
HR (hrvatski): korijen žutog srčanika	IS (íslenska):
HU (magyar): tárnicsgyökér	NO (norsk): gentianarot
IT (italiano): Genziana radice	

European Union 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^{2, 3}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC</p> <p><i>Gentiana lutea</i> L., radix (gentian root)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations⁴</p> <p>a) Comminuted herbal substance</p> <p>b) Dry extract (DER 4.5-5.5:1), extraction solvent ethanol 53% V/V</p> <p>c) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V</p> <p>d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% V/V</p>

3. Pharmaceutical form

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

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

³ The material complies with the Ph. Eur. monograph (ref.: 0392)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product for temporary loss of appetite.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for mild dyspeptic/gastrointestinal disorders.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration⁵

Well-established use	Traditional use
	<p>Posology</p> <p>Indication 1) and 2):</p> <p><i>Adults and Elderly</i></p> <p>a) Single dose: 0.6-2 g of the comminuted herbal substance in 150 ml of boiling water as an infusion 1-3 times per day</p> <p>Daily dose: 0.6-6 g</p> <p>b) Single dose: 240 mg dry extract 2-3 times daily</p> <p>Daily dose: 480-720 mg dry extract</p> <p>c) Single dose: 1 g liquid extract 2-4 times daily</p> <p>Daily dose: 2-4 g liquid extract</p> <p>d) Single dose: 1 ml tincture 1-3 times daily</p> <p>Daily dose: 1-3 ml tincture</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 2 weeks during the use of the medicinal product, a doctor</p>

⁵ 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>or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Indication 1) and 2)</p> <p>Oral use.</p> <p>Indication 1)</p> <p>The liquid preparations a), c), and d) are to be taken ½ hour before meal.</p> <p>Correspondingly, the solid dosage form b) is to be taken 1 hour before meal due to the additional mechanism of disintegration of the solid form.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

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>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>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.</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
	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
	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.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	Traditional use
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product.</p> <p>Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p> <p>For some xanthenes which are among the constituents of <i>Gentiana lutea</i>, positive results have been reported in the AMES test (pre-incubation method).</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

27 March 2018