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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Curcuma longa* L. (*C. domestica* Valetton), rhizoma

Draft

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First revision	
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<p>BG (bulgarski): Куркума, коренище CS (čeština): kořen kurkumy dlouhé DA (dansk): Gurkemeje DE (Deutsch): Curcumawurzelstock EL (elliniká): κουρκούμης μακράς ρίζωμα EN (English): turmeric ES (español): cúrcuma longa, rizoma de ET (eesti keel): kollajuure juurikas FI (suomi): maustekurkuma, maavarsi FR (français): curcuma long (rhizome de) HR (hrvatski): kurkumin podanak HU (magyar): indiai kurkuma gyökértörzs IT (italiano): Curcuma rizoma</p>	<p>LT (lietuvių kalba): Dažinių ciberžolių šakniastiebiai LV (latviešu valoda): Garās kurkumas saknenis MT (Malti): riżoma tat-turmerik NL (Nederlands): geelwortel PL (polski): Kłącze kurkumy PT (português): curcuma RO (română): rizom de turmeric SK (slovenčina): podzemok kurkumy pravej SL (slovenščina): korenika kurkume SV (svenska): gurkmeja, jordstam IS (íslenska): NO (norsk): gurkemeierot</p>
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European Union herbal monograph on *Curcuma longa* L., rhizoma

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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC <i>Curcuma longa</i> L., rhizoma (turmeric root)</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>a) Powdered herbal substance</p> <p>b) Comminuted herbal substance</p> <p>c) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 70% (V/V)</p> <p>d) Dry extract (DER 13-25:1), extraction solvent ethanol 96% (V/V)</p> <p>e) Dry extract (DER 5.5-6.5:1), extraction solvent ethanol 50% (V/V)</p> <p>f) 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>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (ref. 2543).

Well-established use	Traditional 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
	<p>Traditional herbal medicinal product used for the relief of digestive disturbances, such as feelings of fullness, slow digestion and flatulence.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and Elderly</i></p> <p>Daily dose</p> <p>a) Powdered herbal substance: 1.5-3.0 g daily;</p> <p>d) Dry extract (13-25:1): 90-162 mg, divided in 2-5 partial doses daily;</p> <p>Single dose</p> <p>b) Herbal tea: 0.5-1.0 g comminuted herbal substance in 150 ml of boiling water as an infusion, 2-3 times daily;</p> <p>c) Tincture (1:10): 0.5-1 ml, 3 times daily;</p> <p>e) Dry extract (5.5-6.5:1): 100-200 mg, 2 times daily;</p> <p>f) Tincture (1:5): 10 ml once daily or 5 ml in 60 ml water, 3 times daily;</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>

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
	<p data-bbox="810 255 1018 282">Duration of use</p> <p data-bbox="810 311 1414 450">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.</p> <p data-bbox="810 535 1145 562">Method of administration</p> <p data-bbox="810 591 916 618">Oral use</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 data-bbox="810 1028 1422 1131">The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p data-bbox="810 1160 1422 1299">Due to possible stimulation on bile secretion <i>Curcuma longa</i> is not recommended in case of obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary diseases.</p> <p data-bbox="810 1328 1401 1431">If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1460 1422 1632">For tinctures 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
	Mild symptoms of dry mouth, flatulence and gastric irritation 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

Well-established use	Traditional use
	Directive 2001/83/EC as amended.

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 as amended, unless necessary for the safe use of the product.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

21 November 2017