25 September 2018
EMA/HMPC/329755/2017
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Curcuma longa* L., rhizoma

Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2008 November 2008
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	6 November 2008
End of consultation (deadline for comments)	15 March 2009
Re-discussion in MLWP	July 2009 September 2009 November 2009
Adoption by HMPC Monograph (EMEA/HMPC/456845/2009) AR (EMEA/HMPC/456848/2008) List of references (EMEA/HMPC/456910/2008) Overview of comments received during the public consultation (EMEA/HMPC/401918/2009) HMPC Opinion (EMEA/HMPC/678921/2009)	12 November 2009
First systematic review	
Discussion in Working Party on European Union monographs and list (MLWP)	March 2017 May 2017 July 2017 September 2018
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	21 November 2017
End of consultation (deadline for comments)	15 March 2017
Re-discussion in MLWP	March 2018
Adoption by HMPC	25 September 2018

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

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Curcuma longa* L.; Curcuma longae rhizoma; turmeric root

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

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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Curcuma longa* L., rhizoma (turmeric root) i) Herbal substance Not applicable ii) Herbal preparations a) Powdered herbal substance b) Comminuted herbal substance c) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 70% (V/V) d) Dry extract (DER 13-25:1), extraction solvent ethanol 96% (V/V) e) Dry extract (DER 5.5-6.5:1), extraction solvent ethanol 50% (V/V) f) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V)

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

[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 European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used for the relief of digestive disturbances, such as feelings of fullness, slow digestion and flatulence. 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) Powdered herbal substance: 0.5-1 g, 2-3 times daily; b) Herbal tea: 0.5-1.0 g comminuted herbal substance in 150 ml of boiling water as an infusion, 2-3 times daily; c) Tincture (1:10): 0.5-1 ml, 3 times daily; d) Dry extract (DER 13-25:1): 90-162 mg, divided in 2-5 doses daily; e) Dry extract (DER 5.5-6.5:1): 100-200 mg, 2 times daily; f) Tincture (1:5): 10 ml once daily or 5 ml in 60 ml water, 3 times daily; 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

[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
	consulted. **Method of administration** Oral use

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
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Due to possible stimulation on bile secretion *Curcuma longa* is not recommended in case of obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary diseases. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. 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.

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.

Well-established use	Traditional use
	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.

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
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the

Well-established use	Traditional use
	safe use of the product. Adequate 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

25 September 2018