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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Curcuma xanthorrhiza* Roxb. (*C. xanthorrhiza* D. Dietrich), rhizoma

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2013
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	14 May 2013
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 September 2013
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<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Curcuma xanthorrhiza</i> Roxb. ( <i>C. xanthorrhiza</i> D. Dietrich), rhizoma; <i>Curcumae xanthorrhizae</i> rhizoma; Javanese Turmeric
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# Community herbal monograph on *Curcuma xanthorrhiza* Roxb. (*C. xanthorrhiza* D. Dietrich), rhizoma

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1,2</sup>

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Curcuma xanthorrhiza</i> Roxb. (<i>C. xanthorrhiza</i> D. Dietrich), rhizoma (Javanese Turmeric)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>A. Comminuted herbal substance</p> <p>B. Dry extract (DER 20-50:1), extraction solvent ethanol 96% (v/v);</p> <p>C. Dry extract (DER 9-12:1), extraction solvent acetone.</p>

## 3. Pharmaceutical form

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

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

<sup>2</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2008:1441).

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used for symptomatic treatment 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 administration<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adults and elderly:</i></p> <p>A) Herbal tea: single dose 1 g of comminuted herbal substance in 100 ml of boiling water as herbal infusion 3 times daily;</p> <p>B) Dry extract (DER 20-50: 1) extraction solvent ethanol: single dose 8-13 mg, 3 times daily;</p> <p>C) Dry extract (DER 9-12: 1), extraction solvent acetone: single dose 50-100 mg, 2 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> <p><b>Duration of use</b></p> <p>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><b>Method of administration</b></p> <p>Oral use.</p>

<sup>3</sup> 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).

### 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>Due to the possible stimulation on bile secretion <i>Curcuma xanthorrhiza</i> is not recommended in case of obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary diseases.</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>

### 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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

### 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 gastrointestinal symptoms such as 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 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.  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

28 January 2014