EUROPEAN MEDICINES AGENCY
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

Draft

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|---|---|
| BG (bălgarski): Яванска куркума, коренище | LT (lietuvių kalba): Geltonšaknių ciberžolių šakniastiebiai |
| CS (čeština): oddenek kurkumy žlutokořenné | LV (latviešu valoda): Javas kurkumas saknenis |
| DA (dansk): Gurkemeje, javanesisk | MT (malti): Riżoma tat-Turmerik ta' Ġava |
| DE (Deutsch): Javanische Gelbwurz | NL (nederlands): Javaanse Geelwortel |
| EL (elliniká): ρίζωμα ξανθορρίζης | PL (polski): Kłącze kurkumy jawajskiej |
| EN (English): Javanese Turmeric | PT (português): Curcuma-de-java |
| ES (espanol): Cúrcuma, rizoma de | RO (română): |
| ET (eesti keel): tsitveri-kollajuure juurikas | SK (slovenčina): Podzemok kurkumy jávskej |
| FI (suomi): jaavan kurkuma | SL (slovenščina): korenika javanske kurkume |
| FR (français): Temoe-lawacq (rhizome de) | SV (svenska): Gurkmeja, javanesisk |
| HU (magyar): Jávai kurkuma gyökértörzs | *IS (íslenska)*: |
| IT (italiano): Curcuma di Giava rizoma | *NO (norsk):* Java-gurkemeie |


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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[1,2]

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

## 3. Pharmaceutical form

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

[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.: 1441).

# 4. Clinical particulars

## *4.1. Therapeutic indications*

| Well-established use | **Traditional use** |
|---|---|
| | Traditional herbal medicinal product used for symptomatic treatment of digestive disturbances, such as feelings of fullness, slow digestion and flatulence.<br><br>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**<br><br>*Adults and elderly:*<br><br>A) Herbal tea: single dose 1 g of comminuted herbal substance in 100 ml of boiling water as herbal infusion 3 times daily;<br><br>B) Dry extract (DER 20-50:1) extraction solvent ethanol: single dose 8-13 mg, 3 times daily;<br><br>C) Dry extract (DER 9-12:1), extraction solvent acetone: single dose 50-100 mg, 2 times daily.<br><br>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').<br><br>**Duration of use**<br><br>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.<br><br>**Method of administration**<br><br>Oral use. |

[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).

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

## 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. |

## 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.<br><br>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.<br><br>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

14 May 2013