EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Zingiber officinale* Roscoe, rhizoma

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	November 2010 January 2011 March 2011
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BG (bălgarski): Джинджифил, коренище CS (čeština): Zázvorový oddenek DA (dansk): Ingefær DE (Deutsch): Ingwerwurzelstock EL (elliniká): Ζιγγιβέρεως ρίζωμα EN (English): Ginger ES (espanol): Jengibre, rizoma de ET (eesti keel): Ingverijuurikas FI (suomi): Inkivääri FR (français): Gingembre (rhizome de) HU (magyar): Gyömbér gyökértörzs IT (italiano): Zenzero rizoma	LT (lietuvių kalba): Imbierų šakniastiebiai LV (latviešu valoda): Ingvera saknenis MT (malti): Ġinġer NL (nederlands): Gemberwortel PL (polski): Kłącze imbiru PT (português): Gengibre RO (română): Rizom de ghimbir SK (slovenčina): Ďumbierový podzemok SL (slovenščina): Korenika pravega ingverja SV (svenska): Ingefära *IS (íslenska)*: *NO (norsk):* Ingefær

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Community herbal monograph on *Zingiber officinale* Roscoe, 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 marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended *Zingiber officinale* Roscoe, rhizoma (ginger) i) Herbal substance Not applicable. ii) Herbal preparations Powdered herbal substance	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Zingiber officinale* Roscoe, rhizoma (ginger) i) Herbal substance Not applicable. ii) Herbal preparations Powdered herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
Herbal preparations in solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	Herbal preparations in solid dosage forms for oral 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
Herbal medicinal product for the prevention of nausea and vomiting in motion sickness.	Indication 1) Traditional herbal medicinal product for the symptomatic relief of motion sickness. Indication 2) Traditional herbal medicinal product for

1 The material complies with the Ph. Eur. monograph (ref.:07/2008:1522).

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

Well-established use	Traditional use
	symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. *Posology and method of administration*

Well-established use	Traditional use
Posology *Adults and Elderly* 1 - 2 g 1 hour before start of travel. 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** **Method of administration** Oral use.	**Posology** Indication 1) *Adolescents, Adults and Elderly* 750 mg half an hour before travelling. *Children between 6 and 12 years of age* 250 or 500 mg half an hour before travelling The use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2) *Adults and Elderly* 180 mg three times daily as necessary. 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** Indication 1) If the symptoms persist longer than 5 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 2) 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. **Method of administration** Oral use.

4.3. *Contraindications*

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

4.4. *Special warnings and precautions for use*

Well-established use	Traditional use
The use is not recommended in adolescents and children below 18 years due to insufficient data on safety and efficacy. If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.	If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 1) The use in children under 6 years of age has not been established due to lack of adequate data. Indication 2) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.

4.5. *Interactions with other medicinal products and other forms of interaction*

Well-established use	Traditional use
None reported.	None reported.

4.6. *Fertility, pregnancy and lactation*

Well-established use	Traditional use
A moderate amount of data on pregnant women (n =490) indicates no malformative or feto/ neonatal toxicity of ginger root. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3 'Preclinical safety data'). As a precautionary measure it is preferable to avoid the use during pregnancy. In the absence of sufficient data, the use during lactation is not recommended.	A moderate amount of data on pregnant women (n =490) indicates no malformative or feto/ neonatal toxicity of ginger root. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3 'Preclinical safety data'). As a precautionary measure it is preferable to avoid the use during pregnancy. In the absence of sufficient data, the use during 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.	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
Minor gastrointestinal complaints, particularly stomach upset, eructation, dyspepsia and nausea have been reported. Frequency: common (≥1/100 and <1/10). If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.	Minor gastrointestinal complaints, particularly stomach upset, eructation, dyspepsia and nausea have been reported. Frequency: common (≥1/100 and <1/10). 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.	No case of overdose has been reported.

5. Pharmacological properties

5.1. *Pharmacodynamic properties*

Well-established use	Traditional use
Pharmacotherapeutic group: Other antiemetics Proposed ATC code: A04AD	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
No data available.	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
Reproductive and developmental toxicity has been investigated in 3 studies in rats. One study demonstrated advanced skeletal development and increased embryo resorption with the administration of ginger tea (20 g/l and 50 g/l) during gestation days 6-15. Another study using dried powder extract in dosages of 500 and 1000 mg/kg/day during gestation days 5-15 found increased embryo resorption. No maternal toxicity or gross foetal toxicity or defects were observed. One repeated dose toxicity study in rats (600	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. Reproductive and developmental toxicity has been investigated in 3 studies in rats. One study demonstrated advanced skeletal development and increased embryo resorption with the administration of ginger tea (20 g/l and 50 g/l) during gestation days 6-15. Another study using dried powder extract in dosages of 500 and 1000 mg/kg/day during gestation days 5-15 found

Well-established use	Traditional use
mg/kg per day of an aqueous extract of ginger root for 6 days) demonstrated increased testicular weight and increased levels of testosterone in the testes. Another study, in which rats were administered ginger rhizome powder in daily dosages of 50 and 100 mg/kg for 20 days, did not demonstrate any changes in morphology or weight of testes compared to control rats. Chronic toxicity studies have not raised suspicion of other organ changes. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.	increased embryo resorption. No maternal toxicity or gross foetal toxicity or defects were observed. One repeated dose toxicity study in rats (600 mg/kg per day of an aqueous extract of ginger root for 6 days) demonstrated increased testicular weight and increased levels of testosterone in the testes. Another study, in which rats were administered ginger rhizome powder in daily dosages of 50 and 100 mg/kg for 20 days, did not demonstrate any changes in morphology or weight of testes compared to control rats. Chronic toxicity studies have not raised suspicion of other organ changes. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
Not applicable.	Not applicable.

7. Date of compilation / last revision

27 March 2012