EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Zingiber officinale* Roscoe, rhizoma

Draft

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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 travel sickness. Indication 2) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic

[1]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
	gastro-intestinal 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** If the symptoms persist longer than 5 days during the use of the medicinal product, a doctor or a pharmacist should be consulted. **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 under 6 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.	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. 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.	None reported.

4.6. 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'). Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and 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'). 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	No studies on the effect on the ability to drive and

Well-established use	Traditional use
use machines have been performed.	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 2-3%. 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 2-3%. 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	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.

Well-established use	Traditional use
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.	

6. Pharmaceutical particulars

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

7. Date of compilation/last revision

12 July 2011