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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Zingiber officinale* Roscoe, rhizoma Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	November 2010 January 2011 March 2011
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First systematic review	
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; well-established medicinal use; traditional use; <i>Zingiber officinale</i> Roscoe, rhizoma; Zingiberis rhizoma; ginger
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BG (bългарski): Джинджифил, коренище	LT (lietuvių kalba): Imbierų šakniastiebiai
CS (čeština): Zázvorový oddenek	LV (latviešu valoda): Ingvera sakneņis
DA (dansk): Ingefær	MT (malti): Ġinġer
DE (Deutsch): Ingwerwurzelstock	NL (nederlands): Gemberwortel
EL (elliniká): Ζιγγιβέρωσ ρίζωμα	PL (polski): Kłącze imbiru
EN (English): Ginger	PT (português): Gengibre
ES (español): Jengibre, rizoma de	RO (română): Rizom de ghimbir
ET (eesti keel): Ingverijuurikas	SK (slovenčina): Ďumbierový podzemok
FI (suomi): Inkivääri	SL (slovenščina): Korenika pravega ingverja
FR (français): Gingembre (rhizome de)	SV (svenska): Ingefära
HR (hrvatski): đumbir	IS (íslenska): Engifer
HU (magyar): Gyömbér gyökértörzs	NO (norsk): Ingefær
IT (italiano): Zenzero rizoma	

European Union 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 <i>Zingiber officinale</i> Roscoe, rhizoma (ginger)	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Zingiber officinale</i> Roscoe, rhizoma (ginger)
i) Herbal substance	i) Herbal substance
Not applicable.	Not applicable.
ii) Herbal preparations	ii) Herbal preparations
Powdered herbal substance	a) Powdered herbal substance
	b) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 90%
	c) Tincture (ratio of herbal substance to extraction solvent 1:2), extraction solvent ethanol 90%

3. Pharmaceutical form

Well-established use	Traditional use
Herbal preparations in solid dosage forms for oral use.	Herbal preparations in solid or liquid dosage forms for oral use.
The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	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.: 1522).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
<p>Herbal medicinal product for the prevention of nausea and vomiting in motion sickness.</p>	<p>Indication 1) Traditional herbal medicinal product for the symptomatic relief of motion sickness.</p> <p>Indication 2) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence.</p> <p>Indication 3) Traditional herbal medicinal product used for temporary loss of appetite.</p> <p>Indication 4) Traditional herbal medicinal product used for relief of minor articular pain.</p> <p>Indication 5) Traditional herbal medicinal product used for the relief of symptoms of common cold.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
<p>Posology</p> <p><i>Adults and Elderly</i></p> <p>1 - 2 g 1 hour before start of travel.</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>Duration of use</p> <p>Single use before travel.</p> <p>Method of administration</p>	<p>Posology</p> <p>Indication 1)</p> <p>a) Powdered herbal substance</p> <p><i>Adolescents, Adults and Elderly</i></p> <p>500-750 mg half an hour before travelling.</p> <p><i>Children between 6 and 12 years of age</i></p> <p>250-500 mg half an hour before travelling</p>

Well-established use	Traditional use
Oral use.	<p>The use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Indication 2)</p> <p><i>Adults and Elderly</i></p> <p>a) Powdered herbal substance 0.18-1 g 3 times daily.</p> <p>b) Tincture 1:10 1.5-3 ml 3 times daily</p> <p>c) Tincture 1:2 0.25-0.5 ml 3 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>Indication 3), 4) and 5)</p> <p><i>Adults and Elderly</i></p> <p>a) Powdered herbal substance 0.25-1 g 3 times daily.</p> <p>b) Tincture 1:10 1.5-3 ml 3 times daily</p> <p>c) Tincture 1:2 0.25-0.5 ml 3 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>Duration of use</p> <p>Indication 1)</p> <p><i>Adolescents, Adults and Elderly</i></p> <p>Single use before travel. If the travel will continue for more than 4 hours, an additional dose may be taken every 4th hour, if needed, up to a daily dose of 2.5 g.</p> <p><i>Children between 6 and 12 years of age</i></p>

Well-established use	Traditional use
	<p>Single use before travel. If the travel will continue for more than 4 hours, an additional dose may be taken every 4th hour, if needed, up to a daily dose of 1.5 g.</p> <p>Indication 2) and 3)</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>Indication 4)</p> <p>If the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 5)</p> <p>If the symptoms persist more than one week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

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
<p>The use is not recommended in adolescents and children below 18 years due to insufficient data on safety and efficacy.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.</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> <p>Indication 1)</p> <p>The use in children under 6 years of age has not been established due to lack of adequate data.</p> <p>Indication 2-5)</p>

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>Indication 4)</p> <p>Articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor.</p> <p>Indication 2-5)</p> <p>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.</p>

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

Well-established use	Traditional use
None known.	None known.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
<p>A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) 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').</p> <p>As a precautionary measure it is preferable to avoid the use during pregnancy.</p> <p>Safety during lactation has not been established. In the absence of sufficient data, the use during lactation is not recommended.</p> <p>No fertility data available.</p>	<p>A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) 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').</p> <p>As a precautionary measure it is preferable to avoid the use during pregnancy.</p> <p>Safety during lactation has not been established. In the absence of sufficient data, the use during 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
Zingiberis rhizoma has no or negligible influence on the ability to drive and use machines.	Zingiberis rhizoma has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Well-established use	Traditional use
Gastrointestinal disorders: Stomach upset, eructation, dyspepsia, heartburn and nausea. Frequency: common ($\geq 1/100$ to $< 1/10$). Immune system disorders/Skin and subcutaneous tissue disorders: Hypersensitivity. Frequency not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.	Gastrointestinal disorders: Stomach upset, eructation, dyspepsia, heartburn and nausea. Frequency: common ($\geq 1/100$ to $< 1/10$). Immune system disorders/Skin and subcutaneous tissue disorders: Hypersensitivity. Frequency not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist 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 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
<p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p> <p>Studies in mice and rats showed inconsistent results.</p> <p>Repeat dose studies in pregnant rodents showed increased embryo resorption after dosing of ginger powder or aqueous extracts. The doses used are comparable to a range from slightly above to a few times higher than human therapeutic dosage. At higher doses, advanced skeletal development, maternal toxicity, a reduced number of live foetuses and implantation sites was observed. Another study in rats dosed with an ethanolic extract of ginger showed no adverse effects.</p> <p>In male rats, increases in testicular weight and levels of testosterone were observed after 8 days treatment with an aqueous ginger extract at doses comparable to roughly twice human therapeutic doses.</p>	<p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p> <p>Studies in mice and rats showed inconsistent results.</p> <p>Repeat dose studies in pregnant rodents showed increased embryo resorption after dosing of ginger powder or aqueous extracts. The doses used are comparable to a range from slightly above to a few times higher than human therapeutic dosage. At higher doses, advanced skeletal development, maternal toxicity, a reduced number of live foetuses and implantation sites was observed. Another study in rats dosed with an ethanolic extract of ginger showed no adverse effects.</p> <p>In male rats, increases in testicular weight and levels of testosterone were observed after 8 days treatment with an aqueous ginger extract at doses comparable to roughly twice human therapeutic doses.</p>

6. Pharmaceutical particulars

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

7. Date of compilation/last revision

29 May 2024