



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Initial assessment	
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First revision	
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Keywords	Committee on Herbal Medicinal Products; HMPC; European Union herbal monographs; herbal medicinal products; traditional herbal medicinal products; well-established medicinal use; traditional use; <i>Zingiber officinale</i> Roscoe, rhizoma; <i>Zingiberis rhizoma</i> ; ginger
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BG (bългарски): Джинджифил, коренище	LT (lietuvių kalba): Imbierų šakniastiebiai
CS (čeština): zázvorový oddenek	LV (latviešu valoda): Ingvera saknenis
DA (dansk): Ingefær	MT (malti): ginger
DE (Deutsch): Ingwerwurzelstock	NL (nederlands): Gemberwortel
EL (elliniká): ζιγγιβέρεως 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): podzemok d'umbieru
FI (suomi): inkivääri, juurakko	SL (slovenščina): korenika pravega ingverja
FR (français): gingembre (rhizome de)	SV (svenska): ingefära, jordstam
HR (hrvatski): đumbirov podanak	IS (íslenska):
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) 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 <i>Zingiber officinale</i> Roscoe, rhizoma (ginger) i) Herbal substance Not applicable. ii) Herbal preparations a) Powdered herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 90% V/V c) Tincture (ratio of herbal substance to extraction solvent 1:2), extraction solvent ethanol 90% V/V

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 or liquid dosage forms for oral use. 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
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 symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence. Indication 3) Traditional herbal medicinal product used for temporary loss of appetite. Indication 4) Traditional herbal medicinal product used for relief of minor articular pain. Indication 5) Traditional herbal medicinal product used for the relief of symptoms of common cold. 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 <i>Adults and Elderly</i> 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 Single use before travel. Method of administration Oral use.	Posology Indication 1) a) Powdered herbal substance <i>Adolescents, Adults and Elderly</i> 500-750 mg half an hour before travelling. <i>Children between 6 and 12 years of age</i> 250-500 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').

Well-established use	Traditional use
	<p data-bbox="810 253 970 282">Indication 2)</p> <p data-bbox="810 309 1034 338"><i>Adults and Elderly</i></p> <p data-bbox="810 365 1181 394">a) Powdered herbal substance</p> <p data-bbox="810 421 1090 450">0.18-1 g 3 times daily.</p> <p data-bbox="810 477 1011 506">b) Tincture 1:10</p> <p data-bbox="810 533 1082 562">1.5-3 ml 3 times daily</p> <p data-bbox="810 589 995 618">c) Tincture 1:2</p> <p data-bbox="810 645 1121 674">0.25-0.5 ml 3 times daily</p> <p data-bbox="810 701 1393 804">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 data-bbox="810 831 1114 860">Indications 3), 4) and 5)</p> <p data-bbox="810 887 1034 916"><i>Adults and Elderly</i></p> <p data-bbox="810 943 1181 972">a) Powdered herbal substance</p> <p data-bbox="810 999 1090 1028">0.25-1 g 3 times daily.</p> <p data-bbox="810 1055 1011 1084">b) Tincture 1:10</p> <p data-bbox="810 1111 1082 1140">1.5-3 ml 3 times daily</p> <p data-bbox="810 1167 995 1196">c) Tincture 1:2</p> <p data-bbox="810 1223 1121 1252">0.25-0.5 ml 3 times daily</p> <p data-bbox="810 1279 1393 1382">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 data-bbox="810 1408 1016 1438">Duration of use</p> <p data-bbox="810 1464 970 1494">Indication 1)</p> <p data-bbox="810 1520 1193 1550"><i>Adolescents, Adults and Elderly</i></p> <p data-bbox="810 1576 1398 1718">Single use before travel. If the travel will continue for more than 4 hours, an additional dose may be taken every fourth hour, if needed, up to a daily dose of 2.5 g.</p> <p data-bbox="810 1744 1299 1774"><i>Children between 6 and 12 years of age</i></p> <p data-bbox="810 1800 1398 1942">Single use before travel. If the travel will continue for more than 4 hours, an additional dose may be taken every fourth hour, if needed, up to a daily dose of 1.5 g.</p> <p data-bbox="810 1968 1069 1998">Indications 2) and 3)</p>

Well-established use	Traditional use
	<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>Indications 2-5)</p> <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>

Well-established use	Traditional use
	<p>Indications 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
<p>Gastrointestinal disorders: Stomach upset, eructation, dyspepsia, heartburn and nausea. Frequency: common ($\geq 1/100$ to $< 1/10$).</p>	<p>Gastrointestinal disorders: Stomach upset, eructation, dyspepsia, heartburn and nausea. Frequency: common ($\geq 1/100$ to $< 1/10$).</p>

Well-established use	Traditional use
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.	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
Results from oral repeat dose toxicity studies (up to 12 months) of ethanolic ginger extracts indicate that doses which induce any potentially toxic effects are higher than what would normally be administered to humans. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. Studies in mice and rats showed inconsistent results. Repeat dose studies in pregnant rodents showed increased embryo resorption after dosing of ginger powder or aqueous extracts. The doses	Results from oral repeat dose toxicity studies (up to 12 months) of ethanolic ginger extracts indicate that doses which induce any potentially toxic effects are higher than what would normally be administered to humans. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. Studies in mice and rats showed inconsistent results. Repeat dose studies in pregnant rodents showed increased embryo resorption after dosing of ginger powder or aqueous extracts.

Well-established use	Traditional use
<p>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>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

07 May 2025