Community herbal monograph on *Zingiber officinale* Roscoe, rhizoma

Draft

<table>
<thead>
<tr>
<th>Event</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion in Working Party on Community monographs and Community list (MLWP)</td>
<td>November 2010 to January 2011</td>
</tr>
<tr>
<td>Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation</td>
<td>12 July 2011</td>
</tr>
<tr>
<td>End of consultation (deadline for comments). Comments should be provided using this template to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a></td>
<td>15 December 2011</td>
</tr>
<tr>
<td>Rediscussion in Working Party on Community monographs and Community list (MLWP)</td>
<td></td>
</tr>
<tr>
<td>Adoption by Committee on Herbal Medicinal Products (HMPC)</td>
<td></td>
</tr>
</tbody>
</table>

**Keywords**

- Herbal medicinal products; HMPC; Community herbal monographs; well-established medicinal use; traditional use; *Zingiber officinale* Roscoe; Zingiberis rhizoma, ginger

<table>
<thead>
<tr>
<th>Language</th>
<th>Translation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BG (bălgarski):</td>
<td>Джинджифил, коренище</td>
</tr>
<tr>
<td>CS (čeština):</td>
<td>zázvorový oddenek</td>
</tr>
<tr>
<td>DA (dansk):</td>
<td>Ingefær</td>
</tr>
<tr>
<td>DE (Deutsch):</td>
<td>Ingwerwurzelstock</td>
</tr>
<tr>
<td>EL (elliniká):</td>
<td>Ζιγγιβέρεως ρίζωμα</td>
</tr>
<tr>
<td>EN (English):</td>
<td>Ginger</td>
</tr>
<tr>
<td>ES (espanol):</td>
<td>Jengibre, rizoma de</td>
</tr>
<tr>
<td>ET (eesti keel):</td>
<td>ingverjuurikas</td>
</tr>
<tr>
<td>FI (suomi):</td>
<td></td>
</tr>
<tr>
<td>FR (français):</td>
<td>Gingembre (rhizome de)</td>
</tr>
<tr>
<td>HU (magyar):</td>
<td>Gyömbér gyökértörzs</td>
</tr>
<tr>
<td>IT (italiano):</td>
<td>Zenzero rizoma</td>
</tr>
<tr>
<td>LV (latviešu valoda):</td>
<td>Ingvera saknenis</td>
</tr>
<tr>
<td>MT (malti):</td>
<td>Ginger</td>
</tr>
<tr>
<td>NL (nederlands):</td>
<td>Gemberwortel</td>
</tr>
<tr>
<td>PL (polski):</td>
<td>Klącze imbiru</td>
</tr>
<tr>
<td>PT (português):</td>
<td>Gengibre</td>
</tr>
<tr>
<td>RO (română):</td>
<td><em>rizom de ghimbir</em></td>
</tr>
<tr>
<td>SK (slovenčina):</td>
<td>Žumbierový podzemok</td>
</tr>
<tr>
<td>SL (slovenščina):</td>
<td>korenika pravega ingverja</td>
</tr>
<tr>
<td>SV (svenska):</td>
<td>Ingefära</td>
</tr>
<tr>
<td>IS (íslenska):</td>
<td>Ingefær</td>
</tr>
<tr>
<td>NO (norsk):</td>
<td>Ingefær</td>
</tr>
</tbody>
</table>
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**

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended</td>
<td>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</td>
</tr>
<tr>
<td><em>Zingiber officinale</em> Roscoe, rhizoma (ginger)</td>
<td><em>Zingiber officinale</em> Roscoe, rhizoma (ginger)</td>
</tr>
<tr>
<td>i) Herbal substance</td>
<td>i) Herbal substance</td>
</tr>
<tr>
<td>Not applicable.</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>ii) Herbal preparations</td>
<td>ii) Herbal preparations</td>
</tr>
<tr>
<td>Powdered herbal substance</td>
<td>Powdered herbal substance</td>
</tr>
</tbody>
</table>

**3. Pharmaceutical form**

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herbal preparations in solid dosage forms for oral use.</td>
<td>Herbal preparations in solid dosage forms for oral use.</td>
</tr>
<tr>
<td>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</td>
<td>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</td>
</tr>
</tbody>
</table>

**4. Clinical particulars**

**4.1. Therapeutic indications**

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herbal medicinal product for the prevention of nausea and vomiting in motion sickness.</td>
<td>Indication 1)</td>
</tr>
<tr>
<td></td>
<td>Traditional herbal medicinal product for the symptomatic relief of travel sickness.</td>
</tr>
<tr>
<td></td>
<td>Indication 2)</td>
</tr>
<tr>
<td></td>
<td>Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic</td>
</tr>
</tbody>
</table>

1The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
### Well-established use

<table>
<thead>
<tr>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>gastro-intestinal complaints including bloating, and flatulence.</td>
</tr>
<tr>
<td>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</td>
</tr>
</tbody>
</table>

### 4.2. Posology and method of administration

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Posology</strong></td>
<td><strong>Posology</strong></td>
</tr>
<tr>
<td><strong>Adults and Elderly</strong></td>
<td><strong>Indication 1)</strong></td>
</tr>
<tr>
<td>1 - 2 g 1 hour before start of travel.</td>
<td><strong>Adolescents, Adults and Elderly</strong></td>
</tr>
<tr>
<td>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</td>
<td><strong>Children between 6 and 12 years of age</strong></td>
</tr>
<tr>
<td><strong>Duration of use</strong></td>
<td></td>
</tr>
<tr>
<td>If the symptoms persist longer than 5 days during the use of the medicinal product, a doctor or a pharmacist should be consulted.</td>
<td></td>
</tr>
<tr>
<td><strong>Method of administration</strong></td>
<td><strong>Method of administration</strong></td>
</tr>
<tr>
<td>Oral use.</td>
<td>Oral use.</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypersensitivity to the active substance.</td>
<td>Hypersensitivity to the active substance.</td>
</tr>
</tbody>
</table>

4.4. **Special warnings and precautions for use**

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>None reported.</td>
<td>None reported.</td>
</tr>
</tbody>
</table>

4.6. **Pregnancy and lactation**

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>

4.7. **Effects on ability to drive and use machines**

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>No studies on the effect on the ability to drive and</td>
<td>No studies on the effect on the ability to drive and</td>
</tr>
</tbody>
</table>
### 4.8. Undesirable effects

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor gastrointestinal complaints, particularly stomach upset, eructation, dyspepsia and nausea have been reported. Frequency 2-3%.</td>
<td>Minor gastrointestinal complaints, particularly stomach upset, eructation, dyspepsia and nausea have been reported. Frequency 2-3%.</td>
</tr>
<tr>
<td>If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.</td>
<td>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</td>
</tr>
</tbody>
</table>

### 4.9. Overdose

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>No case of overdose has been reported.</td>
<td>No case of overdose has been reported.</td>
</tr>
</tbody>
</table>

### 5. Pharmacological properties

#### 5.1. Pharmacodynamic properties

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacotherapeutic group: Other antiemetics</td>
<td>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.</td>
</tr>
<tr>
<td>Proposed ATC code: A04AD</td>
<td></td>
</tr>
</tbody>
</table>

#### 5.2. Pharmacokinetic properties

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
</table>

#### 5.3. Preclinical safety data

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>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.</td>
</tr>
</tbody>
</table>
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**

<table>
<thead>
<tr>
<th>Well-established use</th>
<th>Traditional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable.</td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

7. **Date of compilation/last revision**

12 July 2011