



12 November 2013
EMA/HMPC/283630/2012
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Camellia sinensis* (L.) Kuntze, non fermentatum folium

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2012 September 2012 January 2013
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Camellia sinensis</i> (L.) Kuntze, non fermentatum folium, green tea leaf
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BG (bългарски): Зелен чай CS (čeština): Čajovníkový list nefermentovaný DA (dansk): Grøn te DE (Deutsch): Grünteeblätter EL (elliniká): Καμελλίας (Τεΐας) της σινικής φύλλο πράσινο EN (English): Green tea ES (español): Té verde, hoja de ET (eesti keel): roheline tee FI (suomi): vihreätee FR (français): Thé vert (feuille de)HU (magyar): Zöld tea levél HR (hrvatska) : nefermentirani list čajevca IT (italiano): Tè verde (foglia)	LT (lietuvių kalba): Kininių arbatmedžių nefermentuoti lapai LV (latviešu valoda): Tējas krūma nefermentētas lapas MT (malti): Te aħdar NL (nederlands): Groene thee PL (polski): Liść herbaty chińskiej niefermentowany (herbata zielona) PT (português): Chá, folha não fermentada RO (română): Frunză de ceai verde SK (slovenčina): Čajovníkový list, nefermentovaný SL (slovenščina): nefermentirani list čajevca SV (svenska): Te IS (íslenska): NO (norsk): Grønn te
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Community herbal monograph on *Camellia sinensis* (L.) Kuntze, non fermentatum folium

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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Camellia sinensis</i> (L.) Kuntze, non fermentatum folium (green tea leaf)</p> <p>i) Herbal substance</p> <p>Whole dried leaf.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance or comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparations in solid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product for relief of fatigue and sensation of weakness.</p>

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 French Pharmacopoeia monograph, 2010

Well-established use	Traditional use
	The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>a) Herbal tea</p> <p>1.8 – 2.2 g of whole or comminuted herbal substance in 100 – 150 ml of boiling water as a herbal infusion, 3 – 5 times daily.</p> <p>b) powdered herbal substance</p> <p>Single dose:</p> <p>390 mg, 3 times daily (up to 5 times if necessary)</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>If the symptoms persist longer than 1 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
	<p>Hypersensitivity to the active substance(s).</p> <p>Gastric and duodenal ulcers, cardiovascular disorders such as hypertension and arrhythmia, hyperthyroidism.</p>

³ For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

4.4. Special warnings and precautions for use

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>Not recommended before bedtime as it may cause sleep disturbances.</p> <p>If symptoms worsen during the use of the medicinal products a doctor or a qualified health practitioner should be consulted.</p>

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

Well-established use	Traditional use
	<p>Caffeine containing preparations reduce actions of sedative substances and increase side effects caused by sympathomimetic drugs.</p>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>No fertility data available.</p> <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	<p>No studies on the effect on the ability to drive and use machines have been performed.</p>

4.8. Undesirable effects

Well-established use	Traditional use
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

Well-established use	Traditional use
	Overdose (quantities corresponding to more than 300 mg caffeine or 5 cups of tea as a beverage) can lead to restlessness, tremor, and elevated reflex excitability. The first signs of poisoning are vomiting and abdominal spasm.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	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
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended. Caffeine crosses the placenta and is distributed in breast milk.

5.3. Preclinical safety data

Well-established use	Traditional use
	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 and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

12 November 2013