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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *ILEX PARAGUARIENSIS* ST. HIL., FOLIUM

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ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Ilex paraguariensis* St. Hil.; Mate folium; maté

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COMMUNITY HERBAL MONOGRAPH ON *ILEX PARAGUARIENSIS* ST. HIL., FOLIUM

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Ilex paraguariensis* St. Hil., folium (maté) *[only non-roasted leaves according commission E monograph and DAC 2004 M-066 and Pharmacopée française.]*[2,3] i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance.

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea 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 dried material complies with the monograph(s) of DAC 2004 M- 066 and with Pharmacopée française, 10ème édition MATE VERT, janvier 1994.
[3] The content of PAH should be assayed for every batch.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	a) Traditional herbal medicinal product for symptoms of fatigue and sensation of weakness. b) Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. 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* Indication a) Daily dose: Comminuted herbal substance as herbal tea: 2-4 g corresponding to 3 times 1 g herbal substance per day. Indication b) Daily dose: Comminuted herbal substance as herbal tea: 2.5-5 g corresponding to 1 to 2 times 2.5 g herbal substance per day. For tea preparation, pour 150 ml of boiling water over the herbal substance. Steep for 15 minutes stirring frequently. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warning and precautions for use'). **Duration of use** Indication a) 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.

	Indication b) 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(s). Gastric and duodenal ulcers, cardiovascular disorders such as hypertension and arrhythmia, hyperthyroidism. Conditions where a reduced fluid intake is recommended, e.g. obstruction of the urinary tract.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indications a) and b) The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data. Not recommended before bedtime as it may cause sleep disturbances. Indication b) If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur 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
	Persons taking MAO-inhibitor drugs should use mate with caution. Caffeine containing preparations reduce sedatives action and increase side effects caused by sympathomimetic drugs.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	There are no or limited data from use during pregnancy and lactation. The use should be avoided during pregnancy and lactation.

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 use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions 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.

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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

16 July 2009