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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Ilex paraguariensis* St. Hilaire, folium

Final

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End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 December 2009
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BG (bългарски): Лист от мате CS (čeština): DA (dansk): DE (Deutsch): Mateblätter EL (elliniká): Φύλλο Ματέ – Ελαιοπρίνου του Παραγουανού EN (English): maté Leaf ES (español): ET (eesti keel): FI (suomi): FR (français): Maté (feuille de) HU (magyar): mate levél IT (italiano):	LT (lietuvių kalba): Matės lapai LV (latviešu valoda): MT (malti): Weraq tat-te' tal-Paragwaj NL (nederlands): Maté, blad PL (polski): Liść ostrokrzewu paragwajskiego PT (português): Mate, folha RO (română): frunza mate SK (slovenčina): List maté SL (slovenščina): SV (svenska): Mateblad <i>IS (islenska):</i> <i>NO (norsk):</i>
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# Community herbal monograph on *Ilex paraguariensis* St. Hilaire, folium

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1,2</sup>

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Ilex paraguariensis</i> St. Hilaire, folium (maté) <sup>3</sup> 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.

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<b>Indication 1)</b> Traditional herbal medicinal product for symptoms of fatigue and sensation of weakness. <b>Indication 2)</b> Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the

1 The material complies with DAC 2004 M- 066 and with Pharmacopée française, 10ème édition MATE VERT, janvier 1994.

2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

3 The content of polycyclic aromatic hydrocarbons (PAH) should be adequately controlled.

Well-established use	Traditional use
	<p>urinary tract as an adjuvant in minor urinary complaints.</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><b>Posology</b></p> <p><i>Adults</i></p> <p><b>Indication 1)</b></p> <p>Daily dose: Comminuted herbal substance as herbal tea: 2-4 g corresponding to 1 g herbal substance 3 times per day.</p> <p><b>Indication 2)</b></p> <p>Daily dose: Comminuted herbal substance as herbal tea: 2.5-5 g corresponding to 2.5 g herbal substance 1 to 2 times per day.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warning and precautions for use').</p> <p><b>Duration of use</b></p> <p><b>Indication 1)</b></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><b>Indication 2)</b></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><b>Method of administration</b></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> <p>Conditions where a reduced fluid intake is recommended, e.g. obstruction of the urinary tract.</p>

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indications 1) and 2)</p> <p>The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.</p> <p>Not recommended before bedtime as it may cause sleep disturbances.</p> <p>Indication 2)</p> <p>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.</p>

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

Well-established use	Traditional use
	<p>Persons taking MAO-inhibitor drugs should use mate with caution.</p> <p>Caffeine containing preparations reduce sedative action and increase side effects caused by sympathomimetic drugs.</p>

### 4.6. Pregnancy and lactation

Well-established use	Traditional use
	<p>There are no or limited data from use during pregnancy and lactation.</p> <p>Use should be avoided during pregnancy and</p>

Well-established use	Traditional use
	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

Well-established use	Traditional use
	<p>necessary for the safe use of the product.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

6 May 2010