EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2012
EMA/HMPC/897344/2011
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Paullinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke, semen

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	November 2011 January 2012 March 2012
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	22 May 2012
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 October 2012
Rediscussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Paulinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke ; Paulliniae semen; guarana seed

BG (bălgarski):	LT (lietuvių kalba):
CS (čeština): semeno paulinie nápojné	LV (latviešu valoda):
DA (dansk):	MT (malti):
DE (Deutsch): Guaranasamen	NL (nederlands): Guarana
EL (elliniká): Σπέρμα γκουαράνα	PL (polski): Nasienie paulinii gwarany
EN (English): Guarana	PT (português): Guaraná
ES (espanol): Guaraná, semilla de	RO (română):
ET (eesti keel):	SK (slovenčina):
FI (suomi): guarana, siemen	SL (slovenščina): Seme gvarane
FR (français): Guarana (graine de)	SV (svenska): Guarana
HU (magyar): Guaránamag	IS (íslenska):
IT (italiano):	NO (norsk): Guaranafrø

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Community herbal monograph on *Paullinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke, semen

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 registration application of Article 16d(1) of Directive 2001/83/EC as amended *Paullinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke, semen (guarana seed) i) Herbal substance Not applicable. ii) Herbal preparations Powdered herbal substance.

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.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for symptoms of fatigue and sensation of weakness. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

[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. Fr. monograph 'guarana, graine de' (1997).

4.2. Posology and method of administration

Well-established use	**Traditional use**
	Posology *Adults and elderly* Single dose: 450 mg up to 5 times per day 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** 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. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	**Traditional use**
	Hypersensitivity to the active substance. Gastric and duodenal ulcers, cardiovascular disorders such as hypertension and arrhythmias, hyperthyroidism.

4.4. Special warnings and precautions for use

Well-established use	**Traditional use**
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Not recommended before bedtime as it may cause sleep disturbances.

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

Well-established use	**Traditional use**
	Persons taking MAO-inhibitor drugs should use

Well-established use	Traditional use
	Paulliniae semen with caution. Caffeine containing preparations reduce sedative action and increase side effects caused by sympathomimetic drugs.

4.6. Fertility, pregnancy and lactation

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

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

22 May 2012