EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 March 2011
EMA/HMPC/722367/2010
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., semen

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	January 2011 March 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 March 2011
End of consultation (deadline for comments).Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 August 2011
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; *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., semen; Colae semen; cola

BG (bălgarski): Кола, семе
CS (čeština): kolové semeno
DA (dansk): Kolanød
DE (Deutsch): Kolasamen
EL (elliniká): σπέρματα κόλα
EN (English): cola
ES (espanol): Cola, nuez de
ET (eesti keel): koolaseeme
FI (suomi):
FR (français): kola
HU (magyar): Kóladiómag
IT (italiano): Cola (Noci di cola)
LT (lietuvių kalba):
LV (latviešu valoda): Kolas koka sēklas
MT (malti):
NL (nederlands): Kolanoot
PL (polski): Zarodek kola
PT (português): Cola
RO (română): sămânţă de cola
SK (slovenčina): Kolové semeno
SL (slovenščina):
SV (svenska): Kolanöt
IS (íslenska):
NO (norsk): kolanøtt

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Community herbal monograph on *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., 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 *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., semen (cola) i) Herbal substance Not applicable. ii) Herbal preparations a) Powdered herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 60% V/V c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 60% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Powdered herbal substance in solid dosage forms for oral use. Powdered herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1]The material complies with the Ph. Eur. monograph (ref.: 01/2008:1504)
[2]The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

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.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and elderly* a) Powdered herbal substance: 1-3 g, 3 times daily. Herbal tea: 1-3 g of powdered herbal substance in 150 ml of water as a decoction, 3 times daily. b) Liquid extract: 0.6-1.2 ml, 3 times daily. c) Tincture: 1-4 ml, 3 times daily. 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(s). Gastric and duodenal ulcers, cardiovascular disorders such as hypertension and arrhythmia,

	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. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

Well-established use	**Traditional use**
	Patients taking MAO-inhibitor drugs should use Colae semen with caution. Caffeine containing preparations reduce sedative action and increase side effects caused by sympathomimetic drugs.

4.6. Pregnancy and lactation

Well-established use	**Traditional use**
	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

31 March 2011