



22 May 2012  
EMA/HMPC/897341/2011  
Committee on Herbal Medicinal Products (HMPC)

## List of references supporting the assessment of *Paullinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke, semen

Draft

**The Agency acknowledges that copies of the underlying works used to produce this monograph were provided for research only with exclusion of any commercial purpose.**

Andersen T, Fogh J. Weight loss and delayed gastric emptying following a South American herbal preparation in overweight patients. *J Hum Nutr Diet*. 2001; 14(3):243-250

Antunes E, Gordo WM, de Oliveira JF, Teixeira CE, Hyslop S, De Nucci G. The relaxation of isolated rabbit corpus cavernosum by the herbal medicine Catuama® and its constituents. *Phytother Res* 2001; 15: 416-421

Antonelli-Ushirobira TM, Kaneshima EN, Gabriel M, Audi EA, Marques LC, Mello JCP. Acute and subchronic toxicological evaluation of the semipurified extract of seeds of guaraná (*Paullinia cupana*) in rodents. *Food Chem. Toxicol.* 2010; 48(7):1817–1820

Avato P, Pesante MA, Fanizzi FP, Santos CA. Seed oil composition of *Paullinia cupana* var. *sorbilis* (Mart.) Ducke. *Lipids* 2003; 38: 773-780

Baumann TW, Schulthess BH, Hanni K. Guarana (*Paullinia cupana*) rewards seeds disperses without intoxicating them by caffeine. *Phytochemistry* 1995; 39:1063-1070

Basile A, Ferrara L, Del Pezzo M, Mele G, Sorbo S, Bassi P, Montesano D. Antibacterial and antioxidant activities of ethanol extract from *Paullinia cupana* Mart. *J Ethnopharmacol* 2005; 102:32-36

Bérubé-Parent S, Pelletier C, Doré J, Tremblay A. Effects of encapsulated green tea and Guarana extracts containing a mixture of epigallocatechin-3-gallate and caffeine on 24 h energy expenditure and fat oxidation in men. *Br J Nutr* 2005; 94(3):432-436

Blumenthal M, Busse WR, Goldberg A, Gruenwald J, et al., editors. The Complete German Commission E Monographs. American Botanical Council, Austin Texas 1998, 140-141



Blumenthal M. Herbal Medicine – Expanded Commission E Monographs. Integrative Medicine Communications Publishers, 2000, 72-74

Bruneton J. Pharmacognosy – Phytochemistry – Medicinal Plants. Intercept Ltd. Londres – Paris – New York, 1999, 1084-1086

Burdock GA, Carabin IG, Crincoli CM. Safety assessment of kola nut extract as a food ingredient. *Food Chem Toxicol* 2009; 47:1725-32

Calixto JB, Cabrini DA. Herbal medicine Catuama® induces endothelium-dependent and -independent vasorelaxant action on isolated vessels from rats, guinea-pigs and rabbits. *Phytother Res* 1997; 11:32-38

Campos AR, Barros AIS Santos FA, Rao VSN. Guarana (*Paullinia cupana* Mart.) offers protection against gastric lesions induced by ethanol and indometacin in rats. *Phytother Res* 2003; 17:1199-1202

Campos AR, Barros AIS, Albuquerque FAA, Leal LKAM, Rao VSN. Acute effects of guarana (*Paullinia cupana* Mart.) on mouse behavior in forced swimming and open field tests. *Phytother Res* 2005; 19:441-443

Cannon ME, Cooke CT, McCarthy JS. Caffeine-induced cardiac arrhythmia: an unrecognised danger of healthfood products. *Med J Aust (MJA)* 2001; 174:520-521

Da Costa Miranda V, Trufelli DC, Santos J, Campos MP, Nobuo M, Da Costa Miranda M , Schlinder F, Riechelmann R, Del Giglio A. Effectiveness of guaraná (*Paullinia cupana*) for postradiation fatigue and depression: Results of a pilot double-blind randomized study. *J. Altern. Complement. Med.* 2009; 15(4): 431-433 (only the abstract)

de Oliveira JF, Avila AS, Braga ACS, de Oliveira MBN, Boasquevisque EM, Jales RL et al. Effect of extract of medicinal plants on the labeling of blood elements with technetium-99m and on the morphology of red blood cells: I – a study with *Paulinia cupana*. *Fitoterapia* 2002; 73:305-312

de Oliveira Campos MP, Riechelmann R, Martins LC, Hassan BJ, Casa FBA, Giglio AD. Guarana (*Paullinia cupana*) improves fatigue in breast cancer patients undergoing systemic chemotherapy. *J Altern Complement Med* 2011; 17(6):505-512

Duke JA, Bogenschutz-Godwin MJ, duCellier J, K. Duke PA. Medicinal Herbs, Handbook of medicinal herbs 2<sup>nd</sup> edition, CRC PRESS 1985

ESCOP Monographs. 2nd Edition *Paullinia semen*. European Scientific Cooperative on Phytotherapy, editor. Georg Thieme Verlag, Stuttgart, Supplement 2009

Espinola EB, Dias RF, Mattei R, Carlini EA. Pharmacological activity of guarana (*Paullinia cupana* Mart.) in laboratory animals. *J Ethnopharmacol* 1997; 55:223-229

Freitas RS, Moreno SRF, Lima-Filho GL, Fonseca AS, Bernardo-Filho M. Effect of a commercial extract of *Paullinia cupana* (guarana) on the binding of 99mTc-DMSA on blood constituents: an *in vivo* study. *Appl. Rad. Isotop.* 2007; 65(5):528-533

Fukumasu H, de Silva TC, Avanzo JL, de Lima CE, Mackowiak II, Attoch A et al. Chemopreventive effects of *paullinia cupana* Mart. Var. *sorbillis*, the guarana, on mouse hepatocarcinogenesis. *Cancer Lett* 2006; 233:158-164 (only the abstract)

Fukumasu H, Avanzo JL, Heidor R, Silva TC, Atroch A, Moreno FS, Dagli MLZ. Protective effects of guarana (*Paullinia cupana* Mart. var. *sorbillis*) against DEN-induced DNA damage on mouse liver. *Food and Chemical Toxicology* 2006; 44:862-867

Fukumasu H, Latorre AO, Zaidan-Dagli ML. *Paullinia cupana* Mart. var. *sorbillis*, guarana, increases survival of Ehrlich ascites carcinoma (EAC) bearing mice by decreasing cyclin-D1 expression and inducing a G0/G1 cell cycle arrest in EAC cells. *Phytother. Res.* 2011; 25(1):11-16

Gruenwald J, Brendler T, Jaenicke C, editors. Guarana. In: PDR for Herbal Medicines, 3<sup>rd</sup> ed. Thomson PDR, Montvale 2007, 425-428

Haskell CF, Kennedy DO, Wesnes KA, Milne AL, Scholey AB. A double-blind, placebo-controlled, multi-dose evaluation of the acute behavioral effects of guarana in humans. *J Psychopharmacol* 2007; 21(1):65-70

Leite RP, Wada RS, Monteiro JC, Predes FS, Dolder H. Protective effect of Guaraná (*Paullinia cupana* var. *sorbillis*) pre-treatment on cadmium-induced damages in adult Wistar testis. *Biol Tr El Res* 2011; 141(1-3):262-274

Majhenič L, Škerget M, Knez Z. Antioxidant and antimicrobial activity of guarana seed extracts. *Food Chem.* 2007; 104(3):1258-1268

Mattei R, Dias RF, Espinola EB, Carlini EA, Barros SBM. Guarana (*Paullinia cupana*): toxic behavioral effects in laboratory animals and antioxidant activity in vitro. *J Ethnopharmacol* 1998; 60:111-116

Martinet A, Hostettmann K, Schultz Y. Thermogenic effects of commercially available plant preparations aimed at treating human obesity. *Phytomedicine* 1999; 6:231-238

Miura T, Tatara M, Nakamura K, Suzuki I. Effect of guarana on exercise in normal and epinephrine-induced glycogenolytic mice. *Biol Pharm Bull* 1998; 21:646-648

Otobone FJ, Sanches ACC, Nagae R, Martins JVC, Sela VR, Palazzo de Mello JC, Audi EA. Effect of lyophilized extracts from guarana seeds [*paullinia cupana* var. *sorbillis* (Mart.) Ducke] on behavioral profiles in rats. *Phytother Res* 2007; 21:541-545

Pagliarussi RS, Freitas LAP, Bastos JK. A quantitative method for the analysis of xanthine alkaloids in *Paullinia cupana* (guarana) by capillary column gas chromatography. *J Sep Sci* 2002; 25:271-274

Paris RR, Moyse H. Guarana. In: Précis de matière médicale. II Pharmacognosie spéciale. Spermaphytes (suite): Angiosperms. Monocotyledones – Dicotyledones. Apetales et Dypetales, 2<sup>nd</sup> ed. Paris: Masson, 1967 Tome II:314-315

Review of Natural Products. 4<sup>th</sup> edition, Wolters Kluwer Health Inc. Missouri USA 2005, 548-550

Pharmacopée Française - French Pharmacopoeia ed (Ph. Fr.). Guarana (graine de). 1997

Roncon CM, Biesdorf De Almeida C, Klein T, Palazzo De Mello JC, Audi EA. Anxiolytic effects of a semipurified constituent of guaraná seeds on rats in the elevated T-maze test. *Planta Medica* 2011; 77(3):236-241

Saldana MDA, Zetzl C, Mohamed RS, Brunner G. Extraction of methylxanthines from guarana seeds, mate leaves and cocoa beans using supercritical carbon dioxide and ethanol. *J Sep Sci* 2002; 25:371-374

Signorello LB, McLaughlin JK. Maternal caffeine consumption and spontaneous abortion: a review of the epidemiologic evidence. *Epidemiology* 2004; 15:229-239

Smith N & Atroch AL. Guaraná's Journey from Regional Tonic to Aphrodisiac and Global Energy Drink. e-Based *Complem Altern Med* 2010; 7(3):279-282

Stahl E. Analyse chromatographique et microscopique des drogues, Société PIC, Fischer Verlag Stuttgart 1970, 220

Steineger E & Haensel R. Lehrbuch der Allgemeinen Pharmacognosie Springer Verlag 1963; 373-375

Vágási K, Degrell P, Késői I, Kovács T, Pintér I, Molnár B, Cseh J, Wittmann I. Acute renal failure caused by plant extract | [Növényi kivonat okozta akut veseelégtelenség] *Orvosi Hetilap* 2007; 148(9):421-424 (only the abstract)

Winkelmayer WC, Stampfer MJ, Willett W, Curham G. Habitual caffeine intake and the risk of hypertension in women. *JAMA* 2005; 294(18):2330-2335.

Yamaguti-Sasaki E, Ito LA, Canteli VCD, Ushirobira TMA, Ueda-Nakamura T, Dias Filho BP, Nakamura CV, De Mello JCP. Antioxidant capacity and *in vitro* prevention of dental plaque formation by extracts and condensed tannins of *Paullinia cupana*. *Molecules* 2007; 12(8):1950-1963

Younkgen H. Text book of Pharmacognosy 5th edition, The Blakiston Company Philadelphia 1943, 548-550