



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 November 2011
EMA/HMPC/722366/2010
Committee on Herbal Medicinal Products (HMPC)

List of references supporting the assessment of *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., semen

Final

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.

Adeyeye EI, Asaolu SS, Aluko AO. Amino acid composition of two masticatory nuts (*Cola acuminata* and *Garcinia kola*) and a snack nut (*Anacardium occidentale*). *Int J Food Sci Nutr* 2007; 58: 241-9

Adeyeye EI, Ayejuyo OO. Chemical composition of *Cola acuminata* and *Garcinia kola* seeds grown in Nigeria. *International Journal of Food Sciences and Nutrition* 1994; 45: 223-30

Ajarem JS, Ahmad M. Effect of consumption of fresh kola-nut extract by female mice on the post-natal development and behaviour of their offspring. *J King Saudi Univ* 1994; 6: 41-50

Ajarem JS. Effects of fresh kola-nut extract (*Cola nitida*) on the locomotor activities of male mice. *Acta Physiol Pharmacol Bulg* 1990; 16: 10-5

Atawodi SE, Mende P, Pfundstein B, Preussmann R, Spiegelhalder B. Nitrosatable amines and nitrosamide formation in natural stimulants: *Cola acuminata*, *C. nitida* and *Garcinia kola*. *Food Chem Toxicol* 1995; 33: 625-30

Atawodi SE, Pfundstein B, Haubner R, Spiegelhalder B, Bartsch H, Owen RW. Content of polyphenolic compounds in the Nigerian stimulants *Cola nitida* ssp. *alba*, *Cola nitida* ssp. *rubra* A. Chev, and *Cola acuminata* Schott & Endl and their antioxidant capacity. *J Agric Food Chem* 2007; 55: 9824-8

Atolaye BO, Adebayo MA, Jagha OOO, Olonisakin A, Agbo CO. Evaluation of the potency of certain substances as antioxidants in the assessment of red cell viability. *Journal of Medicinal Plant Research* 2009; 3: 485-92

Bech BH, Obel C, Henriksen TB, Olsen J. Effect of reducing caffeine intake on birth weight and length of gestation: randomised controlled trial. *BMJ* 2007; 334: 409

Benie T, Duval J, Thieulant ML. Effects of some traditional plant extracts on rat oestrous cycle compared with Clomid. *Phytother Res* 2003; 17: 748-55



Blumenthal M, Busse WR, Goldberg A, Gruenwald J, Hall T, Riggins W, Rister R, Klein S. The Complete German Commission E Monographs. The American Botanical Council, Austin, Texas 1998, 113-4

Blumenthal M. Herbal Medicine – Expanded Commission E Monographs. Integrative Medicine Communications Publishes, 2000; 72-4

Boudjeko T, Rihouey C, Ndoumou DO, El Hadrami I, Lerouge P, Driouich A. Characterisation of cell wall polysaccharides, arabinogalactans-proteins (AGPs) and phenolics of *Cola nitida*, *Cola acuminata* and *Garcinia kola* seeds. *Carbohydrate Polymers* 2009; 78: 820-7

Boylan SM, Cade JE, Kirk SF, Greenwood DC, White KL, Shires S, Simpson NA, Wild CP, Hay AW. Assessing caffeine exposure in pregnant women. *Br J Nutr* 2008; 100: 875-82

Bradley PR. British Herbal Compendium: Volume 1: A Handbook of scientific information on widely used plant drugs. British Herbal Medicine Association, 1992; 64-65

British Herbal Pharmacopoeia 1974. Cola monograph. British Herbal Medicine Association, London 1971

British Herbal Pharmacopoeia. 4th ed. British Herbal Medicine Association, Exeter 1996; 61-2

Bruneton J. Pharmacognosy – Phytochemistry – Medicinal Plants. Intercept Ltd. Londres – Paris – New York 1998; 1081-3

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

Chukwu LO, Odiete WO, Briggs LS. Basal metabolic regulatory responses and rhythmic activity of mammalian heart to aqueous kola nut extracts. *African Journal of Biotechnology* 2006; 5: 484-6

Daels-Rakotoarison DA, Kouakou G, Gressier B, Dine T, Brunet C, Luyckx M, Bailleul F, Trotin F. Effects of a caffeine-free *Cola nitida* nuts extract on elastase/alpha-1-proteinase inhibitor balance. *Journal of Ethnopharmacology* 2003; 89: 143-50

Eteng MU, Eyong EU, Akpanyung EO, Agiang MA, Aremu CY. Recent advances in caffeine and theobromine toxicities: a review. *Plant Foods Hum Nutr* 1997; 51: 231-43

European Pharmacopoeia 7th ed. Colae semen. Council of Europe. 01/2008:1504 corrected 6.0

Evans WC. Trease and Evans Pharmacognosy. W. B. Saunders 2002. 388

FDA. Listing of Food Additive.

<http://www.fda.gov/Food/FoodIngredientsPackaging/FoodAdditives/FoodAdditiveListings/ucm091048.htm> [accessed Nov. 2011]

Fontenot K, Naragoni S, Claville M, Gray W. Characterization of Bizzy nut extracts in estrogen-responsive MCF-7 breast cancer cells. *Toxicology and Applied Pharmacology* 2007; 220: 25-32

Genetox hit for caffeine (<http://toxnet.nlm.nih.gov>) on November 12, 2010

Glaister M, Howatson G, Abraham CS, Lockey RA, Goodwin JE, Foley P, McInnes G. Caffeine supplementation and multiple sprint running performance. *Med Sci Sports Exerc* 2008; 40: 1835-40

Heinrich M, Barnes J, Gibbons S, Williamson EM. Fundamentals of Pharmacognosy and Phytotherapy. Churchill Livingstone, 2004; 239-40

Hogervorst E, Bandelow S, Schmitt J, Jentjens R, Oliveira M, Allgrove J, Carter T, Gleeson M. Caffeine improves physical and cognitive performance during exhaustive exercise. *Med Sci Sports Exerc* 2008; 40: 1841-51

- Ibu JO, Iyama AC, Ijije CT, Ishmael D, Ibeshi M, Nwokediuko S. The effect of cola acuminata and cola nitida on gastric acid secretion. *Scand J Gastroenterol Suppl* 1986; 124: 39-45
- Ikegwuonu FI, Aire TA, Ogwuegbu SO. Effects of kola-nut extract administration on the liver, kidney, brain, testis and some serum constituents of the rat. *J Appl Toxicol* 1981; 1: 292-4
- Ishidate M, Sofuni T, Yoshikawa K, Hayashi M, Nohmi T, Sawada M, Matsuoka A. Primary mutagenicity screening of food additives currently used in Japan. *Food Chem Toxicol* 1984; 22: 623-36 (only abstract available)
- Kamatenesi-Mugisha M, Oryem-Origa H. Traditional herbal remedies used in the management of sexual impotence and erectile dysfunction in western Uganda. *Afr Health Sci* 2005; 5: 40-9
- Kubata BK, Nagamune K, Murakami N, Merkel P, Kabututu Z, Martin SK, Kalulu TM, Huq M, Yoshida M, Ohnishi-Kameyama M, Kinoshita T, Duszenko M, Urade Y. Kola acuminata proanthocyanidins: a class of anti-trypanosomal compounds effective against Trypanosoma brucei. *Int J Parasitol* 2005; 35: 91-103
- Kuczkowski KM. Caffeine in pregnancy. *Arch Gynecol Obstet* 2009; 280: 695-8
- Lans CA. Ethnomedicines used in Trinidad and Tobago for urinary problems and diabetes mellitus. *J Ethnobiol Ethnomed* 2006; 2: 45
- Lans C. Ethnomedicines used in Trinidad and Tobago for reproductive problems. *J Ethnobiol Ethnomed* 2007; 3: 13
- Leviton A, Cowan L. A review of the literature relating caffeine consumption by women to their risk of reproductive hazards. *Food Chem Toxicol* 2002; 40: 1271-310
- Liston J. Breastfeeding and the use of recreational drugs - alcohol, caffeine, nicotine and marijuana. *Breastfeed Rev* 1998; 6: 27-30
- Magkos F, Kavouras SA. Caffeine use in sports, pharmacokinetics in man, and cellular mechanisms of action. *Crit Rev Food Sci Nutr* 2005; 45: 535-6
- Morton JF. Widespread tannin intake via stimulants and masticatories, especially guarana, kola nut, betel vine, and accessories. *Basic Life Sci* 1992; 59: 739-65
- Nawrot P, Jordan S, Eastwood J, Rotstein J, Hugenholtz A, Feeley M. Effects of caffeine on human health. *Food Addit Contam* 2003; 20: 1-30
- Niemenak N, Onomo PE, Fotso, Lieberei R, Ndoumou. Purine alkaloids and phenolic compounds in three Cola species and Garcinia kola grown in Cameroon. *South African Journal of Botany* 2008; 74: 629-38
- Odebode AC. Phenolic compounds in the kola nut (Cola nitida and Cola acuminata) (Sterculiaceae) in Africa. *Revista de Biologia Tropical* 1996; 44: 513-5
- Osim EE, Arthur SK, Etta KM. Influence of kola nuts (Cola nitida alba) on in vivo secretion of gastric acid in cats. *International Journal of Pharmacognosy* 1991; 29: 215-220 (only abstract available)
- Peck JD, Leviton A, Cowan LD. A review of the epidemiologic evidence concerning the reproductive health effects of caffeine consumption: a 2000-2009 update. *Food Chem Toxicol* 2010; 48: 2549-76.
- Practice Committee of the American Society for Reproductive Medicine in collaboration with the Society for Reproductive Endocrinology and Infertility. Optimizing natural fertility. *Fertil Steril* 2008; 90: S1-S6

Scotto G, Maillard C, Vion-dury J, Balansard G, Jadot G. Behavioral effects resulting from sub-chronic treatment of rats with extract of fresh stabilized cola seeds. *Pharmacology, Biochemistry, and Behavior* 1987; 26: 841–5 (only abstract available)

Seitz R, et al. Cola. In: Hagers Handbuch der Pharmazeutischen Praxis. Band 4. Drogen A-D. (Ed.: Hänsel R, Rimpler H, Keller K, Schneider G.) Springer-Verlag, Berlin – Heidelberg 1992; 940-6

Signorello LB, McLaughlin JK. Maternal caffeine consumption and spontaneous abortion: a review of the epidemiologic evidence. *Epidemiology* 2004; 15: 229-39

Solipuram R, Koppula S, Hurst A, Harris K, Naragoni S, Fontenot K, Gray W. Molecular and biochemical effects of a kola nut extract on androgen receptor-mediated pathways. *J Toxicol* 2009; 530279 Epub 2008 Oct 13

Thomson Micromedex. Healthcare series. Caffeine. In Drug interaction for the health care professional. Vol. 1. USP DI 27th ed. 2007, 665

Umoren EB, Osim EE, Udoh PB. The comparative effects of chronic consumption of kola nut (*Cola nitida*) and caffeine diets on locomotor behaviour and body weights in mice. *Niger J Physiol Sci* 2009; 24: 73-8

Vaille A, Balansard G, Jadot G. Effects of a subacute treatment in rats by a fresh cola extract on EEG and pharmacokinetics. *Pharmacology, Biochemistry and Behavior* 1993; 45: 791-6 (only abstract available)

Weng X, Odouli R, Li DK. Maternal caffeine consumption during pregnancy and the risk of miscarriage: a prospective cohort study. *Am J Obstet Gynecol* 2008; 198: 279.e1-8