This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes
- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant’s discretion.
- The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant.

Date October 7, 2014

Proper name(s)
- *Coffea arabica* L. (Rubiaceae) (USDA 2013) and/or *Coffea canephora* Pierre ex A. Froehner (Rubiaceae) (USDA 2013)

Common name(s)
Green coffee bean extract (Kozuma et al. 2005)

Source material(s)
Seed (Bean) (Thom 2007; Kozuma et al. 2005)

Route(s) of administration
Oral

Dosage form(s)
- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
Use(s) or Purpose(s)  Statement(s) to the effect of

- Could be a complement to a healthy lifestyle that incorporates a calorie-reduced diet and regular physical activity for individuals involved in a weight management program (Thom 2007; Dellalibera et al. 2006).
- Helps maintain healthy blood pressure levels (Mubarak et al. 2012; Watanabe et al. 2006; Kozuma et al. 2005).
- Provides antioxidants (Farah et al. 2008; Castellucio et al. 1995).

Dose(s)

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Weight Management

400-1000 mg extract per day, providing 180-500 mg chlorogenic acids and up to 40 mg caffeine per day. Note that chlorogenic acids potency must be 45 – 50% (Thom 2007; Dellalibera et al. 2006).

Blood pressure and Cardiovascular health

Up to 1000 mg extract per day, providing 50-500 mg chlorogenic acids and up to 40 mg caffeine per day (Thom 2007; Watanabe et al. 2006; Kozuma et al. 2005).

Antioxidant

Up to 1000 mg extract per day, providing up to 500 mg chlorogenic acids and 40 mg caffeine per day (Thom 2007).

Duration of use

No statement required.
Risk information Statement(s) to the effect of

Caution(s) and warning(s)

If you are breastfeeding, consult a health care practitioner prior to use.

Contraindication(s)

If you are pregnant, do not use this product.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- The finished product specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.
- The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

References cited


References reviewed


Vinson JA, Burnham BR, Nagendran MV. Randomized, double-blind, placebo-controlled, linear dose, crossover study to evaluate the efficacy and safety of a green coffee bean extract in overweight subjects. Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy 2012;5:21-27.