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: November 15, 2017

Proper name(s):


Common name(s):


Source material(s):

Leaf (Nagao et al. 2005; Chantre and Lairon 2002)

Route(s) of administration:

Oral

Dosage form(s):
The acceptable pharmaceutical dosage forms include, but not limited to capsules, chewable (e.g., gummies, tablets), liquids, powders, strips or tablets.

This monograph is not intended to include foods or food-like dosage forms such as beverages, bars or chewing gums.

Use(s) or Purpose(s):

- Source of antioxidants for the maintenance of good health (Camargo et al. 2006; Coimbra et al. 2006; Henning et al. 2004; Nakagawa et al. 1999; Van het Hof et al. 1997).
- To be used with a program of reduced intake of dietary calories and increased physical activity (if possible) to help in weight management (Nagao et al. 2005; Westerterp-Plantenga et al. 2005; Chantre and Lairon 2002; Dulloo et al. 1999).

Dose(s):

Subpopulation(s):

Adults (≥ 18 years)

Antioxidant:

Extracts providing up to 690 mg total catechins, and no more than 150 mg caffeine, per day (Nagao et al. 2005; Henning et al. 2004; Nakagawa et al. 1999).

Weight management:

Extracts providing 136-300 mg (-)-epigallocatechin-3-gallate (EGCG) and 75-150 mg caffeine, with an ECGC:caffeine ratio of 1.8:1 to 4:1, per day (Nagao et al. 2005; Westerterp-Plantenga et al. 2005; Chantre and Lairon 2002).

Directions for use:

For all products: Take with food (HC 2017).

Duration of use:

For all products: For use beyond 12 weeks, consult a health care practitioner (Nagao et al. 2005; Westerterp-Plantenga et al. 2005; Chantre and Lairon 2002).

Risk Information:
Caution(s) and warning(s):

For all products:
- If you have a liver disorder, consult a health care practitioner prior to use. Stop use if you develop symptoms of liver trouble such as yellowing of the skin/eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite and consult a health care practitioner (HC 2017; HC 2007a; Molinari et al. 2006; Gloro et al. 2005).
- If you are pregnant or breastfeeding, consult a health care practitioner prior to use (HC 2007b).
- If you have an iron deficiency, consult a health care practitioner prior to use (Cooper et al. 2006; Nelson and Poulter 2004; Zijp et al. 2000).

Contraindication(s):

No statement required.

Known adverse reaction(s):

For all products:
Rare, unpredictable cases of liver injury associated with green tea extract-containing products have been reported (in Canada and internationally) (HC 2017).

Non-medicinal Ingredients:

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

Specifications:

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited:


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