



NATURAL HEALTH PRODUCT

GREEN TEA EXTRACT

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 statements are synonymous. Either term or statement may be selected by the applicant.

Date

September 29, 2022

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
<i>Camellia sinensis</i>	<ul style="list-style-type: none"> ▶ <i>Camellia sinensis</i> extract ▶ Green tea extract ▶ Tea extract ▶ <i>Thea sinensis</i> extract ▶ White tea extract 	<i>Camellia sinensis</i>	Leaf

References: Proper name: USDA 2018; Common names: Westerterp-Plantenga et al. 2005, Henning et al. 2004, McGuffin et al. 2000; Source information: Nagao et al. 2005, Chantre and Lairon 2002.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.



Use(s) or Purpose(s)

- ▶ Source of/Provides antioxidants (Camargo et al. 2006; Coimbra et al. 2006; Henning et al. 2004; Nakagawa et al. 1999; Van het Hof et al. 1997).
- ▶ Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (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 and older

Quantity(ies)

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Antioxidants

Not to exceed 690 milligrams total catechins, and 150 milligrams of caffeine, per day (Nagao et al. 2005; Henning et al. 2004; Nakagawa et al. 1999).

Weight management

136 - 300 milligrams (-)-epigallocatechin-3-gallate (EGCG) and 75 -150 milligrams of caffeine, with an EGCG: caffeine ratio of 1.8:1 to 4:1, per day. Not to exceed 690 milligrams of total catechins (including EGCG) per day (Nagao et al. 2005; Westerterp-Plantenga et al. 2005; Chantre and Lairon 2002).

Direction(s) for use

All products

Take with food (HC 2017).



Duration(s) of use

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 12 weeks (Nagao et al. 2005; Westerterp-Plantenga et al. 2005; Chantre and Lairon 2002).

Risk Information

Caution(s) and warning(s)

All products

- ▶ Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician 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 (HC 2017; Molinari et al. 2006; Gloro et al. 2005).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a liver disorder or an iron deficiency (HC 2017; HC 2007; Cooper et al. 2006; Nelson and Poulter 2004; Zijp et al. 2000).

Contraindication(s)

No statement required.

Known adverse reaction(s)

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.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health*

Products Regulations (NHPR).

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.

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