## **Green Tea Extract**

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GREEN TEA EXTRACT (PDF Version - 120 KB) 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 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 on the label. Date July 25, 2025 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) Camellia sinensis Green tea extract Camellia sinensis Leaf References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013; Westerterp-Plantenga et al. 2005; Henning et al. 2004; 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 antioxidants/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). Restrictions when this monograph is combined with other monographs (Class II and III applications): If a weight management claim is made: Weight management is a long-term process and must therefore, be associated with a long-term intervention. Medicinal ingredient with diuretic properties may be included in weight management products, however no diuretic claim can be applied as it is associated with a short-term duration of use (occasional use only). Stimulant laxatives cannot be present at therapeutic dose in weight management products as their short term duration of use is not compatible with the duration of use for weight management. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Antioxidant Not to exceed 690 milligrams total catechins\* per day, including a maximum of 300 mg epigallocatechin 3-gallate (EGCG); and not to exceed 150 milligrams of caffeine, per day (HC 2023; Nagao et al. 2005; Henning et al. 2004; Nakagawa et al. 1999). \*Note: Total catechins is the sum of all catechin compounds, including epicatechins and other related compounds. For green tea extract, total catechins include, catechin (C), epicatechin (EC), epigallocatechin (EGC), epicatechin gallate (ECG), and epigallocatechin gallate (EGCG). 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 a meal/food (HC 2017). Duration(s) of use All products Ask 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 Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking prescription medications. Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience any new symptoms including yellowing of the eyes or skin, dark urine, nausea, vomiting, stomach pain (HC 2017; Molinari et al. 2006; Gloro et al. 2005). All products (except for weight management) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Weight management Ask a health care practitioner/health care provider/health care

professional/doctor/physician before use if you are breastfeeding. Products providing 40 mg or more caffeine, per day and with a catechins:caffeine ratio lower than 2:1 Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have high blood pressure or glaucoma (Cornelis and El-Sohemy 2007; Chandrasekaran et al. 2005; Noordzij et al. 2005; Avisar et al. 2002; Arya et al. 2000; Jee et al. 1999; Creighton and Stanton 1990). Contraindication(s) Weight management Do not use if you are pregnant (HC 2010). Known adverse reaction(s) No statement required. 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. 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. Example Of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Arya LA, Myers DL, Jackson ND. Dietary caffeine intake and the risk for detrusor instability: a case-control study. Obstetrics and Gynecology 2000;96(1):85-89. Avisar R, Avisar E, Weinberger D. Effect of coffee consumption on intraocular pressure. The Annals of Pharmacotherapy 2002;36(6):992-995. Camargo AE, Daguer DA, Barbosa DS. Green tea exerts antioxidant action in vitro and its consumption increases total serum antioxidant potential in normal and dyslipidemic subjects. Nutrition Research 2006;26:626-631. 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Available from: https://www.canada. ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/notice-modification-list-permitted-s upplemental-ingredients-permit-use-green-tea-extract-supplemental-ingredient-foods/document.html HC 2017: Health Canada. Summary Safety Review on Green Tea Extracts containing natural health products -Assessing the potential risk of liver injury (hepatotoxicity). Ottawa (ON): Health Canada; November 2017. Update: December 2017. [Accessed 2025 june 26]. Available from: https://www.canada.ca/en/health-canada/s ervices/drugs-health-products/medeffect-canada/safety-reviews/green-tea-extract-containing-natural-health-pro ducts-assessing-potential-risk-liver-injury.html HC 2010: Health Canada: Prenatal Nutrition Guidelines for health Professionals: Gestational weight gain [Accessed 2025 June 26]. Available from: https://www.canada.ca /content/dam/hc-sc/migration/hc-sc/fn-an/alt\_formats/pdf/nutrition/prenatal/ewba-mbsa-eng.pdf Health Canada. It's Your Health: Caffeine. Ottawa (ON). [Accessed 2025 June 26]. Available from: https://publications.gc.ca/collections/collection\_2011/sc-hc/H13-7-2-2010-eng.pdf Henning SM, Niu Y, Lee NH, Thames GD, Minutti RR, Wang H, Go VL, Heber D. 2004. Bioavailability and antioxidant activity of tea flavanols after consumption of green tea, black tea, or a green tea extract supplement. American Journal of Clinical Nutrition 2004;80(6):1558-1564. Jee SH, He J, Whelton PK, Suh II, Klag MJ. The effect of chronic coffee drinking on blood pressure: a meta-analysis of controlled clinical trials. Hypertension 1999;33(2):647-652. Molinari M, Watt KD, Kruszyna T, Nelson R, Walsh M, Huang WY, Nashan B, Peltekian K. Acute liver failure induced by green tea extracts: case report and review of the literature. Liver Transplantation 2006;12(12):1892-1895. Nagao T, Komine Y, Soga S, Meguro S, Hase T, Tanaka Y, Tokimitsu I. 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# MEDICINAL INGREDIENT(S)

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

## DOSAGE FORM(S)

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.

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### **RISK INFORMATION**

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking prescription medications. Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience any new symptoms including yellowing of the eyes or skin, dark urine, nausea, vomiting, stomach pain (HC 2017; Molinari et al. 2006; Gloro et al. 2005). All products (except for weight management) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Weight management Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Products providing 40 mg or more caffeine, per day and with a catechins:caffeine ratio lower than 2:1 Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have high blood pressure or glaucoma (Cornelis and El-Sohemy 2007; Chandrasekaran et al. 2005; Noordzij et al. 2005; Avisar et al. 2002; Arya et al. 2000; Jee et al. 1999; Creighton and Stanton 1990). Contraindication(s) Weight management Do not use if you are pregnant (HC 2010). Known adverse reaction(s) No statement required.

#### 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 CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

### **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. Example Of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Camellia sinensis	Green tea extract	Camellia sinensis	Leaf