Health Canada Santé Canada

PRODUIT DE SANTÉ NATUREL

EXTRAIT DE THÉ VERT

La présente monographie vise à servir de guide à l'industrie pour la préparation de demandes de licence de mise en marché (DLMM) et d'étiquettes dans le but d'obtenir une autorisation de mise en marché d'un produit de santé naturel. Elle ne vise pas à être une étude approfondie de l'ingrédient médicinal.

Nota

- Les parenthèses contiennent des éléments d'information additionnels (facultatifs) qui peuvent être inclus dans la DLMM ou sur l'étiquette du produit à la discrétion du demandeur.
- La barre oblique (/) indique que les termes et/ou énoncés sont synonymes. Le demandeur peut utiliser n'importe lequel des termes ou énoncés indiqués.

Date 29 septembre 2022

Nom(s) propre(s), Nom(s) commun(s), Information(s) d'origine

Tableau 1. Nom(s) propre(s), Nom(s) commun(s), Information(s) d'origine

Nom(s) propre(s)	Nom(s) commun(s)	Information(s) d'origine	
		Matière(s) d'origine	Partie(s)
Camellia sinensis	▸ Extrait de *Camellia sinensis* ▸ Extrait de thé ▸ Extrait de *Thea sinensis* ▸ Extrait de thé blanc ▸ Extrait de thé vert	*Camellia sinensis*	Feuille

Références : Nom propre: USDA 2018; Noms communs: Westerterp-Plantenga et al. 2005, Henning et al. 2004, Bruneton 1999; Information d'origine: Nagao et al. 2005, Chantre et Lairon 2002.

Voie d'administration

Orale

Forme(s) posologique(s)

Cette monographie exclut les aliments et les formes posologiques semblables aux aliments tel qu'indiqué dans le document de référence Compendium des monographies.

Les formes posologiques acceptables pour la voie d'administration orale sont indiquées dans la liste déroulante dans le formulaire web de demande de licence de mise en marché pour les

demandes officinales.

Usage(s) ou fin(s)

- Source d'antioxydants/Fournit des antioxydants (Camargo et al. 2006; Coimbra et al. 2006; Henning et al. 2004; Nakagawa et al. 1999; Van het Hof et al. 1997).
- Source d'antioxydants/Fournit des antioxydants qui aident à combattre/à protéger (les cellules) contre/à réduire (les effets oxydatifs des/les dommages oxydatifs causés par/les dommages cellulaires causés par) les radicaux libres (Camargo et al. 2006; Coimbra et al. 2006; Henning et al. 2004; Nakagawa et al. 1999; Van het Hof et al. 1997).
- À utiliser dans le cadre d'un programme qui recommande une réduction de l'apport calorique et une augmentation de l'activité physique (dans la mesure du possible) pour aider à la gestion du poids (Nagao et al. 2005; Westerterp-Plantenga et al. 2005; Chantre and Lairon 2002; Dulloo et al. 1999).

Dose(s)

Sous-population(s)

Adultes 18 ans et plus

Quantité(s)

Antioxydants

Méthodes de préparation : Extraits normalisés (extrait sec, teinture, extrait fluide, décoction, infusion)

Ne pas dépasser 690 milligrammes de catéchines totales, et 150 milligrammes de caféine, par jour (Nagao et al. 2005; Henning et al. 2004; Nakagawa et al. 1999).

Gestion du poids

Méthodes de préparation : Extraits normalisés (extrait sec, teinture, extrait fluide, décoction, infusion)

136 à 300 milligrammes de (-)-épigallocatéchine-3-gallate (EGCG) et 75 à 150 milligrammes de caféine, avec un taux EGCG:caféine de 1,8:1 à 4:1, par jour. Ne pas dépasser 690 milligrammes de catéchines totales (incluant EGCG), par jour (Nagao et al. 2005; Westerterp-Plantenga et al. 2005; Chantre et Lairon 2002).

Mode(s) d'emploi

Tous les produits

Prendre avec de la nourriture (SC 2017).

Durée(s) d'utilisation

Tous les produits

Consulter un praticien de soins de la santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin si l'utilisation se prolonge au-delà de 12 semaines (Nagao et al. 2005; Westerterp-Plantenga et al. 2005; Chantre et Lairon 2002).

Mention(s) de risque

Précaution(s) et mise(s) en garde

Tous les produits

- Cesser l'utilisation si vous développez des symptômes de troubles du foie tels que le jaunissement de la peau/des yeux (jaunisse), des douleurs d'estomac, de l'urine foncée, de la transpiration, de la nausée, une fatigue inhabituelle et/ou une perte d'appétit et consulter un praticien de soins de la santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin (SC 2017; Molinari et al. 2006; Gloro et al. 2005).
- Consulter un praticien de soins de la santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant d'en faire l'usage si vous êtes enceinte ou si vous allaitez.
- Consulter un praticien de soins de la santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant d'en faire l'usage si vous souffrez de troubles du foie ou avez une carence en fer (SC 2017; SC 2007; Cooper et al. 2006; Nelson et Poulter 2004; Zijp et al. 2000).

Contre-indication(s)

Énoncé non requis.

Réaction(s) indésirable(s) connue(s)

Tous les produits

Des cas rares et non prévisibles de lésions du foie associées avec des produits contenant de l'extrait de thé vert ont été rapportés (au Canada et internationalement) (SC 2017).

Ingrédients non médicinaux

Doivent être choisis parmi ceux de la version actuelle de la Base de données des ingrédients des produits de santé naturels (BDIPSN) et respecter les restrictions mentionnées dans cette base de données.

Conditions d'entreposage

Doivent être établies conformément aux exigences décrites dans le *Règlement sur les produits de santé naturels* (RPSN).

Spécifications

- Les spécifications du produit fini doivent être établies conformément aux exigences décrites dans le Guide de référence sur la qualité des produits de santé naturels de la Direction des produits de santé naturels et sans ordonnance (DPSNSO).
- L'ingrédient médicinal doit être conforme aux exigences mentionnées dans la BDIPSN.

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