Health Canada Santé Canada

PRODUIT DE SANTÉ NATUREL

REISHI – *GANODERMA LUCIDUM*

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 25 février 2019

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

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

Nom(s) propre(s)	Nom(s) commun(s)	Matière(s) d'origine		
		Nom(s) propre(s)	Partie(s)	Préparation(s)
Ganoderma lucidum	▸ Reishi ▸ Ganoderma ▸ Ling zhi	*Ganoderma lucidum*	▸ Corps fructifère ▸ Mycélium cultivé ▸ Mycélium	Séchée

Références: Nom propre: CABI 2018, PPRC 2010; Noms communs: PPRC 2010, Bensky et al. 2004, Chen et Chen 2004, McGuffin et al. 2000; Matières d'origine: PPRC 2010, Leung et Foster 2003, Yarnell et al. 2003, Wasser 2002, Flynn et Roest 1995.

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 les catégories d'âge listées dans cette monographie et pour la voie d'administration spécifiée sont indiquées dans le document de référence

Compendium des monographies.

Usage(s) ou fin(s) recommandés

Corps fructifère

- Utilisé en médecine traditionnelle chinoise (MTC) pour disperser les mucosités, enrayer la toux et la respiration sifflante (PPRC 2010; Bensky et al. 2004; Chen et Chen 2004).
- Utilisé en médecine traditionnelle chinoise (MTC) pour nourrir le cœur et renforcer le qi et le sang afin de soigner les déficiences du cœur et de la rate se manifestant par de l'insomnie, des pertes de mémoire, de la fatigue, un manque d'attention et un appétit faible (PPRC 2010; Bensky et al. 2004; Chen et Chen 2004).
- Utilisé en médecine traditionnelle chinoise (MTC) pour renforcer le corps et tonifier le qi (PPRC 2010; Bensky et al. 2004; Chen et Chen 2004).

L'(Les) usage(s) combiné(s) suivant(s) est/sont aussi acceptable(s):

Utilisé en médecine traditionnelle chinoise (MTC) pour renforcer le corps, le qi et le sang afin de soigner les déficiences du cœur et de la rate se manifestant par de l'insomnie, des pertes de mémoire, de la fatigue, un manque d'attention et un appétit faible (PPRC 2010; Bensky et al. 2004; Chen et Chen 2004).

Corps fructifère; Mycélium cultivé; Mycélium

- Source d'antioxydants/Fournit des antioxydants (Wachtel-Galor et al. 2011; Godfrey et al. 2010; Wicks et al. 2007).
- Source de polysaccarides fongiques ayant des propriétés immunomodulatrices (Chan et al. 2009 ; Wasser 2002).
- Utilisé en phytothérapie comme tonique pour le foie (Godfrey et al. 2010, Yarnell et al. 2003; Saunders 2000; Peirce 1999; Belanger 1997; Hsu et al. 1986).
- Utilisé en phytothérapie pour soutenir le système immunitaire (Wachtel-Galor et al. 2011; Godfrey et al. 2010; Ko et Leung 2007; Lin 2005; Chen et Chen 2004; Wachtel- Galor et al. 2004; Hoffmann 2003; Yarnell et al. 2003; Peirce 1999; Belanger 1997; Hsu et al. 1986).
- Utilisé en phytothérapie comme adaptogène pour aider à accroître l'énergie et la résistance au stress (en cas de fatigue mentale ou physique due au stress) (Godfrey et al. 2010; Hobbs 2003; Hoffmann 2003; Leung et Foster 1996).

Nota
Les allégations concernant un usage traditionnel doivent inclure le terme « phytothérapie », « médecine traditionnelle chinoise » ou « Ayurvéda ».

Dose(s)

Sous-population(s)

Adultes 18 ans et plus

Quantité(s)

Antioxydant; Source de polysaccharides

Méthodes de préparation : Sec, poudre, extraits ethanoliques normalisés (extrait sec, teinture, extrait fluide)

Ne pas dépasser 6 grammes de Reishi séché, par jour (Godfrey et al. 2010).

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

Ne pas dépasser 6 grammes de Reishi séché, par jour et 40% de polysaccharides (Godfrey et al. 2010).

Méthode de préparation : Décoction

Ne pas dépasser 15 grammes de Reishi séché, par jour (Wachtel-Galor et al. 2011).

Méthode de préparation : Décoction normalisée

Ne pas dépasser 15 grammes de Reishi séché, par jour et 40% de polysaccharides (Wachtel-Galor et al. 2011).

Tonique du foie; Adaptogène; Médecine traditionnelle chinoise - toux - cœur - tonique du qi

Méthodes de préparation : Sec, poudre, extraits éthanoliques non-normalisés (extrait sec, teinture, extrait fluide)

1,5 à 6 grammes de Reishi séché, par jour (Bensky et al. 2004; Chen et Chen 2004; Hobbs 2003; Upton 2000; Huang 1999).

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

1,5 à 6 grammes de Reishi séché, par jour et ne pas dépasser 40% de polysaccharides (Bensky et al. 2004; Chen et Chen 2004; Hobbs 2003; Upton 2000; Huang 1999).

Méthode de préparation : Décoction

3 à 15 grammes de Reishi séché, par jour (Godfrey et al. 2010; PPRC 2010; Bensky et al. 2004; Chen et Chen 2004).

Méthode de préparation : Décoction normalisée

3 à 15 grammes de Reishi séché, par jour et ne pas dépasser 40% de polysaccharides (Godfrey et al. 2010; PPRC 2010; Bensky et al. 2004; Chen et Chen 2004).

Soutien du système immunitaire

Méthodes de préparation : Teinture, extrait fluide

1,5 à 6 grammes de Reishi séché, par jour (Godfrey et al. 2010).

Méthodes de préparation : Teinture normalisée, extrait fluide normalisée

1,5 à 6 grammes de Reishi séché, par jour et ne pas dépasser 40% de polysaccharides

(Godfrey et al. 2010). Méthode de préparation : Décoction

3 à 15 grammes de Reishi séché, par jour (Wachtel-Galor et al. 2011; Wasser 2002).

Méthode de préparation : Décoction normalisée

3 à 15 grammes de Reishi séché, par jour et ne pas dépasser 40% de polysaccharides (Wachtel-Galor et al. 2011; Wasser 2002).

Nota

- Pour les préparations en poudre qui ne sont pas des extraits, l'allégation 'Utilisé en phytothérapie pour soutenir le système immunitaire' n'est pas appuyée et n'est donc pas acceptable.
- Pour les extraits normalisés, étant donné que les preuves sont principalement basées sur la quantité brute équivalente de Reishi, à la fois la quantité brute équivalente et la concentration maximale de la composante d'activité doivent être respectées.

Mode(s) d'emploi

Prendre avec de la nourriture/un repas pour éviter les problèmes digestifs (Flynn et Roest 1995).

Durée(s) d'utilisation

Énoncé non requis.

Mention(s) de risques

Précaution(s) et mise(s) en garde

Médecine traditionnelle chinoise - toux

Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/ docteur/médecin si les symptômes persistent ou s'aggravent.

Contre-indication(s)

Énoncé non requis.

Réaction(s) indésirable(s) connue(s)

Cesser l'utilisation si une hypersensibilité/allergie se manifeste (derMarderosian et Beutler 2008; Bensky et al. 2004; Gao et al. 2003, 2002).

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

Énoncé non requis.

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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