

## PRODUIT DE SANTÉ NATUREL

### GINSENG À CINQ FOLIOLES - *PANAX QUINQUEFOLIUS*

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

27 janvier 2023

#### 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)	Préparation(s)
<i>Panax quinquefolius</i>	<ul style="list-style-type: none"> <li>▶ Ginseng à cinq folioles</li> <li>▶ Ginseng d'Amérique</li> <li>▶ Ginseng occidentale</li> <li>▶ Sang</li> <li>▶ Shang</li> <li>▶ Xi yang shen</li> </ul>	<i>Panax quinquefolius</i>	Racine	Sèche

Références : Nom propre : USDA 2018; Noms communs : USDA 2018, Marie-Victorin 2002, Small et Catling 1999; Information d'origine : PPRC 2010, Lust 1974, Wren 1956.

#### 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.

### Usages(s) ou fin(s)

- ▶ Utilisé en médecine traditionnelle chinoise (MTC) pour l'insuffisance du *qi* et du *yin*, pour la chaleur interne, pour la toux, pour la présence de sang dans le mucus, pour le feu lors du syndrome d'insuffisance, pour la dysphorie et la fatigue, pour la soif, la bouche et la gorge sèches (PPRC 2010).
- ▶ Utilisé en phytothérapie comme thérapie de soutien pour aider au contrôle du taux de glucose (PPRC 2010, Dascalu et al 2007; Vuksan et al 2000a; Vuksan et al 2000b; Vuksan et al 2000c).
- ▶ Utilisé (traditionnellement) en phytothérapie pour aider à soulager l'agitation et/ou la nervosité (nervin/calmant) (Bartram, 1998; Ellingwood 1998).
- ▶ Utilisé traditionnellement en phytothérapie pour aider à soulager la dyspepsie nerveuse/pour aider à la digestion dans les cas de nervosité et/ou de stress (Bartram 1998; Felter et Lloyd 1983; Wren 1956).
- ▶ Utilisé en phytothérapie comme adaptogène pour aider au maintien du système immunitaire (Upton 2012; Godfrey et al. 2010; Assinewe 2001; Bartram 1998).
- ▶ Utilisé en phytothérapie comme adaptogène pour aider à augmenter l'énergie et la résistance au stress (par ex., dans les cas de fatigue mentale et physique liées au stress) (Upton 2012; Winston and Maimes 2007).

### Nota

Les allégations pour les usages traditionnels doivent inclure le terme « phytothérapie », « médecine traditionnelle chinoise » ou « Ayurvéda ».

### Dose(s)

#### Sous-population(s)

Adultes 18 ans et plus

#### Quantité(s)

*Taux de glucose; Agitation/Nervosité*

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

0,5 à 12 grammes de racine séchée, par jour (Bartram 1998; Felter et Lloyd 1983; Wren 1956).

*Adaptogène – énergie et résistance au stress; Adaptogène – système immunitaire*

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

1 à 3 grammes de racines séchées, par jour (Upton 2012; Winston and Maimes 2007).

*Adaptogène – énergie et résistance au stress*

Méthodes de préparation : Extraits aqueux non-normalisés (extrait sec, décoction, infusion)

6 à 9 grammes de racines séchées, par jour; Ne pas dépasser 3 grammes par dose unique (Winston and Maimes 2007).

*MTC*

Méthodes de préparation : Décoction, Décoction concentrée

2,4 à 9 grammes de racine séchée, par jour (PPRC 2010; Bensky et Gamble 1993).

### **Mode(s) d'emploi**

Énoncé non requis.

### **Durée(s) d'utilisation**

Énoncé non requis.

### **Mention(s) de risque**

#### **Précaution(s) et mise(s) en garde**

- ▶ Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant d'en faire l'usage si vous prenez des anticoagulants ou de la digoxine (Brinker 2010; Elmer et al 2007; Dasgupta et al. 2005; Yuan et al 2004).
- ▶ Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant d'en faire l'usage si vous avez le diabète (Brinker 2010; Dascalu et al 2007; Vuksan et al 2000a; Vuksan et al 2000b; Vuksan et al 2000c).

#### **Contre-indication(s)**

Énoncé non requis.

#### **Réaction(s) indésirable(s) connue(s)**

Énoncé non requis.



## 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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