



PRODUIT DE SANTÉ NATUREL

MILLEPERTUIS – *HYPERICUM PERFORATUM*

Orale

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 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

18 décembre 2018

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)
<i>Hypericum perforatum</i>	<ul style="list-style-type: none">▶ Herbe de la St-Jean▶ Hypericum▶ Millepertuis▶ Millepertuis commun	<i>Hypericum perforatum</i>	Sommité (herbe)	Séchée

Références: Nom propre: USDA 2018; Noms communs: Angheliescu et al. 2006, Gastpar et al. 2006, Szegedi et al. 2005, Wichtl 2004, Brouillet 2002, Bruneton 1999; Matière d'origine: Bradley 2006, Mills et Bone 2005, Hoffmann 2003, Blumenthal et al. 2000, Felten et Lloyd 1983, Wren 1907.

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)

- ▶ Utilisé (traditionnellement) en phytothérapie pour aider à soulager l'agitation et/ou la nervosité (calmant) (Mills et Bone 2005; Hoffmann 2003; Blumenthal et al. 2000; Felter et Lloyd 1983; Grieve 1971).
- ▶ (Utilisé en phytothérapie pour) aide(r) à promouvoir un bon équilibre de l'humeur (Brattström 2009; Anghelescu et al. 2006; Gastpar et al. 2006; Kasper et al. 2006; Fava et al. 2005; Mills et Bone 2005; Szegedi et al. 2005; Uebelhack et al. 2004; ESCOP 2003; Hoffmann 2003; Lecrubier et al. 2002; Volz et al. 2002; Kalb et al. 2001).
- ▶ (Utilisé en phytothérapie pour) aide(r) à soulager les troubles du sommeil qui accompagnent les déséquilibres de l'humeur (Randløv et al. 2006; Wichtl 2004; Friede et al. 2001; Wheatley 1999; Schrader et al. 1998).

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

(Utilisé en phytothérapie pour) aide(r) à promouvoir un bon équilibre de l'humeur et à soulager les troubles du sommeil qui accompagnent les déséquilibres de l'humeur (Brattström 2009; Anghelescu et al. 2006; Gastpar et al. 2006; Kasper et al. 2006; Randløv et al. 2006; Fava et al. 2005; Mills and Bone 2005; Szegedi et al. 2005; Uebelhack et al. 2004; Wichtl 2004; ESCOP 2003; Hoffmann 2003; Lecrubier et al. 2002; Volz et al. 2002; Friede et al. 2001; Kalb et al. 2001; Wheatley 1999; Schrader et al. 1998).

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)

Soulagement de l'agitation et/ou de la nervosité

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



2 à 12,6 grammes de sommités (herbe) séchées, par jour; Ne pas dépasser 4,2 grammes par dose unique (Anghelescu et al. 2006; Wichtl 2004; ESCOP 2003; Blumenthal et al. 2000).

Tous les usages

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

600 à 1800 milligrammes d'extrait, par jour, normalisé à 3 à 6% d'hyperforine et/ou 0,12 à 0,28% d'hypericine; Ne pas dépasser 600 milligrammes d'extrait par dose unique (Anghelescu et al. 2006; Gastpar et al. 2006; Kasper et al. 2006; Fava et al. 2005; Szegedi et al. 2005; Uebelhack et al. 2004; Wichtl 2004; ESCOP 2003; Hoffmann 2003; Lecrubier et al. 2002; Volz et al. 2002; Kalb et al. 2001; Blumenthal et al. 2000; BHP 1983).

Mode(s) d'emploi

Énoncé non requis.

Durée(s) d'utilisation

- ▶ Utiliser pendant au moins 1 semaine afin de pouvoir constater les effets bénéfiques (Papakostas et al. 2007; Kalb et al. 2001).
- ▶ Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/médecin/docteur si l'usage se prolonge au-delà de 18 semaines (Anghelescu et al. 2006; Gastpar et al. 2006; Kasper et al. 2006; Fava et al. 2005; Mills et Bone 2005; Szegedi et al. 2005; Uebelhack et al. 2004; ESCOP 2003; Hypericum Depression Trial Study Group 2002; Lecrubier et al. 2002; Volz et al. 2002; Kalb et al. 2001; BHP 1983).

Mention(s) de risque

Précaution(s) et mise(s) en garde

- ▶ Éviter toute exposition prolongée au soleil, aux rayons ultraviolets (UV) ou rayons UV produits par la luminothérapie (Brinker 2010; Barnes et al. 2007; Mills et Bone 2005; ESCOP 2003; Hoffmann 2003; McGuffin et al. 1997).
- ▶ Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/médecin/docteur si les symptômes persistent ou s'aggravent.
- ▶ Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/médecin/docteur avant d'en faire l'usage si vous êtes enceinte ou si vous allaitez (Brinker 2010; Barnes et al. 2007; Mills et Bone 2005).



- Consulter un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/médecin/docteur avant d'en faire l'usage si vous prenez des médicaments anxiolytiques ou anticonvulsifs, des antihistaminiques, des bronchodilatateurs, des relaxants musculaires et/ou des opiacés (Brinker 2010; Barnes et al. 2007; Mills et Bone 2005; Kawaguchi et al. 2004; Morimoto et al. 2004; Eich-Höchli et al. 2003; Dresser et al. 2003; Hoffman 2003; Markowitz et al. 2003; Xie et al. 2003; Dannawi 2002; Gurley et al. 2002; Spinella et Eaton 2002; Wang et al. 2002; Parker et al. 2001; Wang et al. 2001; Burstein et al. 2000; Nebel et al. 1999).

Contre-indication(s)

Ne pas utiliser ce produit si vous prenez des médicaments anticancéreux, antidépresseurs [par ex., inhibiteurs spécifiques du recaptage de la sérotonine (ISRS)], cardiovasculaires, contraceptifs, des anticoagulants, des agents anti-VIH et/ou des médicaments qui inhibent le système immunitaire (immunosuppresseurs) (Brinker 2010; Barnes et al. 2007; Bradley 2006; Mills et Bone 2005; Murphy et al. 2005; Frye et al. 2004; Hebert et al. 2004; Jiang et al. 2004; Mueller et al. 2004; Smith et al. 2004; Sparreboom et al. 2004; Tannergren et al. 2004; Wichtl 2004; Alscher et Klotz 2003; Bauer et al. 2003; Dresser et al. 2003; ESCOP 2003; Hall et al. 2003; Hoffmann 2003; Pfrunder et al. 2003; Schwarz et al. 2003; Bolley 2002; Gorski et al. 2002; Mathijssen et al. 2002; Ahmed et al. 2001; De Maat et al. 2001; Moschella et Jaber 2001; Roby et al. 2001; Sugimoto et al. 2001; Turton-Weeks 2001; Wang et al. 2001; Barone et al. 2000; Durr et al. 2000; Karlova et al. 2000; Mai et al. 2000; Piscitelli et al. 2000; Ruschitzka et al. 2000; Ernst 1999; Johne et al. 1999; Maurer et al. 1999; Rey and Walter 1998).

Réaction(s) indésirable(s) connue(s)

- Cesser l'utilisation si une hypersensibilité/allergie se manifeste (Barnes et al. 2007; ESCOP 2003).
- Certaines personnes pourraient souffrir de troubles gastro-intestinaux bénins, de nausées, d'agitation et/ou de maux de tête (Barnes et al. 2007; ESCOP 2003).

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 références 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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