

## PRODUIT DE SANTÉ NATUREL

### PRODUITS DE VARECH

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 des ingrédients médicinaux.

#### **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 discréption 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** 28 octobre 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)	Préparation(s)
<i>Ascophyllum nodosum</i>	▶ Knuppetan ▶ Varech norvégien	<i>Ascophyllum nodosum</i>	▶ En entier ▶ Thalle	Sèche
<i>Fucus vesiculosus</i>	▶ Chone marin ▶ Kelpware ▶ Varech noueux ▶ Varech vésiculeux	<i>Fucus vesiculosus</i>	▶ En entier ▶ Thalle	Sèche
<i>Laminaria digitata</i>	▶ Fouet de sorcier ▶ Laminaire digitée ▶ Varech	<i>Laminaria digitata</i>	▶ En entier ▶ Thalle	Sèche
<i>Laminaria japonica</i>	▶ Enchevêtement de mer ▶ Hai dai ▶ Makombu ▶ Varech japonais	<i>Laminaria japonica</i>	▶ En entier ▶ Thalle	Sèche

Références: Noms propres: Guiry et Guiry 2018a,b; Noms communs: TGA 2016, The Biodiversity Committee of Chinese Academy of Science 2013; Informations d'origine: Guiry et Guiry 2018a,b.

## 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)

*Tous les produits*

- ▶ Source d'antioxydants/Fournit des antioxydants (Murphy et al. 2013; FCÉN 2012; Kang et al. 2012; Veena et al. 2008; Veena et al. 2007; Zhang et al. 2007; Jin et al. 2004).
- ▶ 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 (Murphy et al. 2013; FCÉN 2012; Kang et al. 2012; Veena et al. 2008; Veena et al. 2007; Zhang et al. 2007; Jin et al. 2004).

*Produits fournissant 0,8 g ou plus de Fucus vesiculosus par jour*

- ▶ Utilisé traditionnellement en phytothérapie comme un altératif du système glandulaire (Hoffman 2003; Duke 2002; Grieve 1931a,b; Felter et Lloyd 1898).
- ▶ Utilisé en phytothérapie pour soutenir le fonctionnement normal de la glande thyroïde (Bradley 1992; Grieve 1931a,b; Ellingwood 1919).

*Produits normalisés à l'iode*

Selon la monographie des Suppléments de multivitamines/minéraux de la Direction des produits de santé naturels et sans ordonnance (DPSNSO).

## Nota

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

## Dose(s)

### Sous-population(s)

Adultes 18 ans et plus

### Quantité(s)

*Antioxydants*

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

Ne pas dépasser 1 gramme de varech par jour (Barnes et al. 2007; Mills et Bone 2005; Kolb et al. 2004; Duke 2002; BHP 1996; Bradley 1992)

*Fucus vesiculosus : altératif, fonctionnement normal de la glande thyroïde*

0,8 à 1 gramme de *Fucus vesiculosus* par jour (Mills et Bone 2005; Bradley 1992).

*Allégations relatives au iode (monographie des Suppléments de multivitamines/minéraux)*

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

Les ingrédients médicinaux doivent fournir la quantité d'iode minimale indiquée dans la monographie des Suppléments de multivitamines/minéraux de la DPSNSO. L'iode doit être indiqué sur le formulaire de DLMM comme composante d'activité.

### Nota

La quantité totale d'iode fournie par le produit ne doit pas dépasser 800 microgrammes d'iode par jour (IOM 2006).

### Mode(s) d'emploi

Énoncé non requis.

### Duré e(s) d'utilisation

Énoncé non requis.

## Mention(s) de risque

### Précaution(s) et mise(s) en garde

*Tous les produits*

- ▶ 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 (Gardner et McGuffin 2013; Ren et al. 2013; Zhao et al. 2012; Brinker 2010; Gruenwald et al. 2007; Duke 2002).
- ▶ 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 (Brinker 2010; Barnes 2002).

### Contre-indication(s)

Énoncé non requis.

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

Énoncé non requis.

## Ingédients non médicinaux

Doivent être choisis parmi ceux de la version actuelle de la Base de données d'ingrédients de 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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