



PRODUIT DE SANTÉ NATUREL

BÊTA-GLUCANE

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.

Notes

- 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

23 février 2024

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)
bêta-D-Glucane	• beta-D-Glucan	• <i>Avena sativa</i>	• Graine • Son	Isolat
	• bêta-D-Glucane	• <i>Hordeum vulgare</i>		
	bêta-Glucane d'avoine	<i>Avena sativa</i>		

Références: Nom propre: Charlton et al. 2012; EFSA 2011a,b, 2010; Queenan et al. 2007; Braaten et al. 1994; Uusitupa et al. 1992; Noms communs: Charlton et al. 2012; EFSA 2011a,b, 2010; Queenan et al. 2007; Braaten et al. 1994; Uusitupa et al. 1992; Informations d'origine: USDA 2023; Charlton et al. 2012; Queenan et al. 2007.

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)

- Aide à réduire/diminuer le cholestérol LDL (qui est un des facteurs de risque dans le développement des maladies coronariennes) (Charlton et al. 2012; EFSA 2011a,b, 2010; AbuMweiss et al. 2010; SC 2010; Wolever et al. 2010; Delahoy et al. 2009; Queenan et al. 2007; Wood 2007; Biorklund et al. 2005; NECP 2002; Brown et al. 1999; Ripsin et al. 1992).
- Aide à réduire/diminuer le mauvais cholestérol (qui est un des facteurs de risque dans le développement des maladies coronariennes) (Charlton et al. 2012; EFSA 2011a,b, 2010; AbuMweiss et al. 2010; SC 2010; Wolever et al. 2010; Delahoy et al. 2009; Queenan et al. 2007; Wood 2007; Biorklund et al. 2005; NECP 2002; Brown et al. 1999; Ripsin et al. 1992).
- Fournit un soutien pour un métabolisme du glucose (postprandial) sain (dans les deux heures suivant un repas) (EFSA 2011a,b; Ulmius et al. 2011; Granfeldt et al. 2008; Panahi et al. 2007; Biorklund et al. 2005; Kabir et al. 2002).
- Aide à améliorer le métabolisme du glucose (postprandial) (dans les deux heures suivant un repas) (EFSA 2011a,b; Ulmius et al. 2011; Granfeldt et al. 2008; Panahi et al. 2007; Biorklund et al. 2005; Kabir et al. 2002).
- Source de fibres pour le maintien d'une bonne santé (ACIA 2022; IOM 2005). Aide à soutenir et à maintenir un système digestif sain (ACIA 2022; IOM 2005).

Note : Les usages ci-dessus peuvent être combinés sur l'étiquette du produit (par ex., Aide à réduire/diminuer le mauvais cholestérol et à améliorer le métabolisme du glucose).

Dose(s)

Sous-population(s)

Adultes de 18 ans et plus

Quantité(s)

2 à 10 grammes de bêta-glucane, par jour (Charlton et al. 2011; EFSA 2011a,b, 2010; AbuMweiss et al. 2010; Queenan et al. 2007; IOM 2005; Johnston et al. 1998; Braaten et al. 1994; Torronen et al. 1992; Uusitupa et al. 1992).

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

Énoncé non requis.

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*.

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.



EXEMPLE D'INFO-PRODUIT :

Veillez consulter la ligne directrice, [Étiquetage des produits de santé naturels](#) pour plus de détails.

Info-Produit	
Ingrédient médicamenteux dans chaque mesure	
bêta-D-Glucane (<i>Avena sativa</i> – graine)	XX g
Usages	
<ul style="list-style-type: none"> • Aide à réduire/diminuer le mauvais cholestérol qui est un des facteurs de risque dans le développement des maladies coronariennes. • Fournit un soutien pour un métabolisme du glucose sain dans les deux heures suivant un repas. • Source de fibres pour le maintien d'une bonne santé. • Aide à soutenir et à maintenir un système digestif sain. 	
Mises en garde	
Si applicable¹ :	
Allergènes : allergène alimentaire, gluten (source de gluten), sulfites	
Contient de l'aspartame	
Mode d'emploi	
Adultes 18 ans et plus : • Prendre X mesure(s), X fois par jour.	
Autres renseignements	
(Ajoutez les informations d'entreposage)	
Ingrédients non-médicinaux	
Énumérez tous les INM	
Questions? (Appelez) 1-XXX-XXX-XXXX	

¹Cette section peut être retirée du tableau si le produit ne contient pas d'allergène ou d'aspartame.

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