



PRODUIT DE SANTÉ NATUREL

PRODUITS D’HUILES FIXES – 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.

Notes

- Cette monographie n’appuie que les acides gras se retrouvant naturellement dans les huiles fixes, incluant les huiles concentrées mais elle exclut les huiles fixes enrichies avec des acides gras supplémentaires.
- Les préparations contenant des huiles essentielles/volatiles (par ex., celles préparées par distillation) dépassent le cadre de cette monographie.
- Les huiles hydrogénées et partiellement hydrogénées dépassent le cadre de cette monographie.
- Cette monographie peut être utilisée pour appuyer les produits à ingrédient unique ou à ingrédients multiples contenant un ou plusieurs ingrédient(s) médicinal(aux) du tableau 1.
- 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

28 mars 2024

Nom(s) propre(s), Nom(s) commun(s) et Information(s) d’origine

Tableau 1 : Nom(s) propre(s), Nom(s) commun(s) et Information(s) d’origine

Nom(s) propre(s)	Nom(s) commun(s)	Information(s) d’origine	
		Matière(s) d’origine	Partie(s)
<i>Borago officinalis</i>	Huile de bourrache	<i>Borago officinalis</i>	Graine
<i>Camelina sativa</i>	Huile de lin bâtard	<i>Camelina sativa</i>	Graine
<i>Cannabis sativa</i>	Huile de graines de chanvre	<i>Cannabis sativa</i>	Graine
<i>Carthamus tinctorius</i>	Huile de carthame	<i>Carthamus tinctorius</i>	Graine
<i>Cocos nucifera</i>	Huile de noix de coco	<i>Cocos nucifera</i>	Albumen (graine d’angiosperme)
Huile de foie de morue	Huile de foie de morue	Gadidae ¹	Foie
<i>Cucurbita pepo</i>	Huile de graines de citrouille	<i>Cucurbita pepo</i>	Graine
Huile de canola	<ul style="list-style-type: none"> • Huile de canola • Huile de colza 	<ul style="list-style-type: none"> • <i>Brassica napus</i> • <i>Brassica juncea</i> 	Graine



Nom(s) propre(s)	Nom(s) commun(s)	Information(s) d'origine	
		Matière(s) d'origine	Partie(s)
	• Huile de graines de canola	• <i>Brassica rapa</i>	
Huile de poisson ²	Huile de poisson	<ul style="list-style-type: none"> • Ammodytidae • Carangidae • Clupeidae • Engraulidae • Gadidae³ • Osmeridae • Salmonidae • Scombridae 	En entier
<i>Helianthus annuus</i>	Huile de tournesol	<i>Helianthus annuus</i>	Graine
<i>Hippophae rhamnoides</i>	Huile de fruit d'argousier	<i>Hippophae rhamnoides</i>	Fruit
	Huile de graines d'argousier	<i>Hippophae rhamnoides</i>	Graine
Huile de krill	Huile de krill	<ul style="list-style-type: none"> • <i>Euphasia pacifica</i> • <i>Euphausia superba</i> 	En entier
<i>Linum usitatissimum</i>	<ul style="list-style-type: none"> • Huile de lin • Huile de graines de lin 	<i>Linum usitatissimum</i>	Graine
<i>Oenothera biennis</i>	<ul style="list-style-type: none"> • Huile d'onagre • Huile de primrose 	<i>Oenothera biennis</i>	Graine
<i>Olea europaea</i>	Huile d'olive	<i>Olea europaea</i>	Fruit
<i>Prunus dulcis</i>	<ul style="list-style-type: none"> • Huile d'amande • Huile d'amandes douces 	<i>Prunus dulcis</i>	Graine
<i>Ribes nigrum</i>	Huile de pépins de cassis	<i>Ribes nigrum</i>	Graine
<i>Salvia hispanica</i>	Huile de graines de chia	<i>Salvia hispanica</i>	Graine
<i>Schizochytrium</i> spp.	Huile de Schizochytrium	<i>Schizochytrium</i> spp.	En entier
Huile de phoque	Huile de phoque	<ul style="list-style-type: none"> • <i>Cystophora cristata</i> • <i>Erignathus barbatus</i> • <i>Halichoerus grypus</i> • <i>Pagophilus groenlandicus</i> • <i>Phoca vitulina</i> • <i>Pusa hispida</i> 	Petit lard
Huile de calmar	Huile de calmar	<ul style="list-style-type: none"> • <i>Todarodes pacificus</i> • <i>Docidicus gigas</i> • <i>Illex argentinus</i> • <i>Illex illecebrosus</i> 	En entier
<i>Triticum aestivum</i>	Huile de germe de blé	<i>Triticum aestivum</i>	Germe (graine)
<i>Vitis vinifera</i>	Huile de pépins de raisin	<i>Vitis vinifera</i>	Graine

Références: Noms propres: BDIPSN 2023; Noms communs: BDIPSN 2023; Informations d'origine: FCC 2023, ITIS 2023, USP-NF 2023, Ph.Eur 2023, Linnamaa et al. 2010, Yurko-Mauro et al. 2010, Dubois et al. 2007, Callaway et al. 2005, Hoffmann 2003, Yang et al. 1999.

¹ **Huile de foie de morue** : Les noms communs des espèces et non pas la famille peuvent être listés sur l'étiquette.

² **Huile de poisson** : Correspond à l'huile du corps entier d'un ou plus d'espèces des familles listées dans le Tableau 1 dans sa forme naturelle, et/ou sous forme triglycéride/triacylglycérol concentrée et/ou sous forme estérifiée concentrée (BP 2023; Ph.Eur. 2023; Froese and Pauly 2022). Les noms communs des espèces et non pas les familles peuvent être listés sur l'étiquette.

³ **Huile de poisson** : Pour les huiles de poisson incluant des espèces de Gadidae comme matière d'origine, le contenu en vitamine A et D doit être testé afin d'assurer que les doses maximales quotidiennes rencontrent la monographie des Suppléments de multivitamines/minéraux pour chaque groupe d'âge.

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) et Dose(s)

Sous-population(s)

Adulte 18 ans et plus

Quantité(s)

Consulter les tableaux 2 et 3.

Tableau 2 : Usages ou fins, doses quotidiennes associées et composantes d'activité (AL – Acide linoléique; AAL – Acide alpha-linolénique; AEP – Acide eicosapentaénoïque; ADH – Acide docosahexaénoïque; ADP – Acide docosapentaénoïque; AGL-Acide gamma-linolénique; AO – Acide oléique)

Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
Huile de bourrache	Huile fixe non-normalisée	• Source d'acides gras essentiels pour le maintien d'une bonne	Huile : 3,7-5 g	S/O



Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
		santé <ul style="list-style-type: none"> • Source d'acides gras oméga-6 pour le maintien d'une bonne santé • Source d'acide linoléique (LA) pour le maintien d'une bonne santé 		
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 5 g et AL, AAL, AGL et/ou AO selon le tableau 3*	AL, AAL, AGL, AO
Huile de canola	Huile fixe non-normalisée	S/O	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 15 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de caméline	Huile fixe non-normalisée	S/O	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 15 g et AL, AAL, et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de chanvre	Huile fixe non-normalisée	S/O	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 15 g et AL, AAL, AGL et/ou AO selon le tableau 3*	AL, AAL, AGL, AO
Huile de carthame	Huile fixe non-normalisée	S/O	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 15 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de noix de coco	Huile fixe non-normalisée	<ul style="list-style-type: none"> • Source d'antioxydants/Fournis des antioxydants • Source d'antioxydants/Fournis des antioxydants 	Huile : jusqu'à 15 g	S/O



Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
		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		
	Huile fixe normalisée	<ul style="list-style-type: none"> • Source d'antioxydants/Fournis des antioxydants • Source d'antioxydants/Fournis 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 et/ou <ul style="list-style-type: none"> • Selon le tableau 3 	Huile : jusqu'à 15 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de foie de morue	Huile fixe normalisée	Selon la monographie de l'huile de foie de morue	Huile : jusqu'à 4 g et Quantités de AEP, ADH, Vitamine A et Vitamine D selon la monographie de l'huile de foie de morue	AEP, ADH, Vitamine A, Vitamine D



Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
		Selon le tableau 3	Huile : jusqu'à 4 g et Quantités minimales de AEP et/ou ADH selon le tableau 3* et Quantités maximales de AEP, ADH, Vitamine A et Vitamine D selon la monographie de l'huile de foie de morue	AEP, ADH, Vitamine A, Vitamine D
Huile de graines de citrouille	Huile fixe non-normalisée	S/O	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 15 g et AL et/ou AO selon le tableau 3*	AL, AO
Huile de poisson	Huile fixe normalisée	Selon la monographie de l'huile de poisson	Selon la monographie de l'huile de poisson	AEP, ADH
		Selon le tableau 3	Huile : jusqu'à 10 g et AEP et/ou ADH selon le tableau 3*	AEP, ADH
Huile de tournesol	Huile fixe non-normalisée	<ul style="list-style-type: none"> • Source d'antioxydants/Fournis des antioxydants • Source d'antioxydants/Fournis 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 	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	<ul style="list-style-type: none"> • Source d'antioxydants/Fournis des antioxydants 	Huile : jusqu'à 15 g et AL et/ou AO selon le	AL, AO

Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
		<ul style="list-style-type: none"> Source d'antioxydants/Fournis 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 et/ou <ul style="list-style-type: none"> Selon le tableau 3 	tableau* 3*	
Huile de graine d'argousier	Huile fixe non-normalisée	S/O	Huile : jusqu'à 5 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 5 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de fruit d'argousier	Huile fixe non-normalisée	S/O	Huile : jusqu'à 5 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 5 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de krill	Huile fixe normalisée	<ul style="list-style-type: none"> Source d'AEP (acide éicosapentaénoïque) et d'ADH (acide docosahexaénoïque) pour le maintien d'une bonne santé Source d'acides gras oméga-3 pour le maintien d'une bonne santé Source d'acide gras omega-3 tel qu'AEP et ADH 	Huile : jusqu'à 4,1 g et AEP+ADH : 100 mg ou plus	AEP, ADH
		Selon le tableau 3	Huile : jusqu'à 4,1 g et AEP et/ou ADH selon	AEP, ADH

Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
			le tableau 3*	
Huile de lin	Huile fixe non-normalisée	<ul style="list-style-type: none"> • Source d'acide gras essentiel (acide alpha-linolénique (AAL)) pour le maintien d'une bonne santé • Source d'acides gras oméga-3 pour le maintien d'une bonne santé • Source d'acide alpha-linolénique (AAL) pour le maintien d'une bonne santé 	Huile : 0,23-32 g	S/O
		<ul style="list-style-type: none"> • Source d'acide gras essentiel (acide linoléique (AL)) pour le maintien d'une bonne santé • Source d'acides gras essentiels (acide alpha-linolénique (AAL) et acide linoléique (AL)) pour le maintien d'une bonne santé • Source d'acides gras oméga-6 pour le maintien d'une bonne santé • Source d'acide linoléique (AL) pour le maintien d'une bonne santé 	Huile : 7,7-32 g	
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 32 g et/ou AL, AAL et/ou AO selon le tableau 3*	
Huile d'onagre	Huile fixe non-normalisée	<ul style="list-style-type: none"> • Source d'acides gras essentiels pour le maintien d'une bonne santé 	Huile : 1,3-6 g	S/O



Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
		<ul style="list-style-type: none"> • Source d'acides gras oméga-6 pour le maintien d'une bonne santé • Source d'acide linoléique (AL) pour le maintien d'une bonne santé 		
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 6 g et AL, AAL, AGL et/ou OA selon le tableau 3*	AL, AAL, AGL, AO
Huile d'olive	Huile fixe non-normalisée	<ul style="list-style-type: none"> • Source d'antioxydants/Fournis des antioxydants • Source d'antioxydants/Fournis 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 	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	<ul style="list-style-type: none"> • Source d'antioxydants/Fournis des antioxydants • Source d'antioxydants/Fournis 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 	Huile : jusqu'à 15 g et AL et/ou AO selon le tableau 3*	AL, AO



Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
		par) les radicaux libres et/ou • Selon le tableau 3		
Huile d'amande	Huile fixe non-normalisée	S/O	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 15 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de pépins de cassis	Huile fixe non-normalisée	S/O	Huile : jusqu'à 10,5 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 10,5 g et AL, AAL, AGL et/ou AO selon le tableau 3*	AL, AAL, AGL, AO
Huile de chia	Huile fixe non-normalisée	S/O	Huile : jusqu'à 4,5 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 4,5 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de Schizochytrium	Huile fixe normalisée	Aide à soutenir la santé cognitive et/ou les fonctions cérébrales	ADH : 200-2000 mg	AEP, ADH
		Selon le tableau 3	Huile : jusqu'à 5 g et AEP et/ou ADH selon le tableau 3*	
Huile de phoque	Huile fixe normalisée	Selon la monographie de l'huile de phoque	Selon la monographie de l'huile de phoque	AEP, ADH, ADP
		Selon le tableau 3	Huile : jusqu'à 10 g et AEP, ADH et/ou ADP selon le tableau 3*	
Huile de calmar	Huile fixe non-normalisée	S/O	Huile : jusqu'à 5 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 5 g et AEP et/ou ADH selon	AEP, ADH

Ingrédients médicinaux	Méthodes de préparation	Usages ou fins	Doses quotidiennes ¹	Composantes d'activité
			le tableau 3*	
Huile de germe de blé	Huile fixe non-normalisée	<ul style="list-style-type: none"> • Source d'antioxydants/Fournis des antioxydants • Source d'antioxydants/Fournis 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 	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	<ul style="list-style-type: none"> • Source d'antioxydants/Fournis des antioxydants • Source d'antioxydants/Fournis 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 et/ou <ul style="list-style-type: none"> • Selon le tableau 3 	Huile : jusqu'à 15 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO
Huile de pépins de raisin	Huile fixe non-normalisée	S/O	Huile : jusqu'à 15 g	S/O
	Huile fixe normalisée	Selon le tableau 3	Huile : jusqu'à 15 g et AL, AAL et/ou AO selon le tableau 3*	AL, AAL, AO

Références : DPSNSO 2023; Zielinska et al. 2017; Quinn et al. 2010; Yang et al. 1999; Leventhal et al. 1994.

¹La quantité des huiles fixes peut aussi être représentée en quantité volumétrique (c.-à-d. ml) en se basant sur les informations de densités listées en Annexe 1.

*La quantité totale d'un acide gras spécifique (par ex., AL) dans un produit doit rencontrer la dose minimale listée dans le Tableau 3 pour appuyer une allégation de ce tableau. Il n'est pas obligatoire que chaque huile rencontre la dose minimale d'un acide gras spécifique si la quantité totale d'un acide gras dans le produit fini la rencontre.

Tableau 3 : Usages ou fins selon les composantes d'activité - acides gras

Composantes d'activité : acides gras ¹	Usage(s) ou fin(s)	Dose quotidienne minimale ²
AL	<ul style="list-style-type: none"> • Source d'acide linoléique (AL) pour le maintien d'une bonne santé • Source d'acide gras oméga-6 pour le maintien d'une bonne santé • Source d'acide gras essentiel pour le maintien d'une bonne santé 	850 mg
AAL	<ul style="list-style-type: none"> • Source d'acide alpha-linolénique (AAL) pour le maintien d'une bonne santé • Source d'acide gras oméga-3 pour le maintien d'une bonne santé • Source d'acide gras essentiel pour le maintien d'une bonne santé 	80 mg
AL + AAL	Source d'acides gras essentiels pour le maintien d'une bonne santé	850 mg d'AL et 80 mg d'AAL
AEP + ADH ou AEP + ADP ou ADH + ADP ou AEP + ADH + ADP	Source d'acides gras oméga-3 pour le maintien d'une bonne santé	100 mg
AEP	Source d'acide eicosapentaénoïque (AEP) pour le maintien d'une bonne santé	100 mg
ADH	Source d'acide docosahexaénoïque (ADH) pour le maintien d'une bonne santé	100 mg
	<ul style="list-style-type: none"> • Aide à soutenir/maintenir la santé cognitive • Aide à soutenir/maintenir les fonctions cérébrales 	150 mg
	<ul style="list-style-type: none"> • Aide à soutenir/maintenir le fonctionnement des yeux • Aide à soutenir/maintenir la santé oculaire 	200 mg

Composantes d'activité : acides gras ¹	Usage(s) ou fin(s)	Dose quotidienne minimale ²
ADP	Source d'acide docosapentaénoïque (ADP) pour le maintien d'une bonne santé	100 mg
AEP + ADH	<ul style="list-style-type: none"> • Aide à soutenir/maintenir la/une santé cardiovasculaire/du cœur (normale) • Aide à soutenir/maintenir une/les fonction(s) cardiovasculaire(s)/du cœur (normale(s)) 	200 mg
	<ul style="list-style-type: none"> • Aide à soutenir/maintenir les taux normaux de triglycérides/triacyglycérols (sanguins) • Aide à réduire (les taux de)/(les) triglycérides/triacyglycérols (sanguins) 	1000 mg
AGL	Source d'acide gamma-linoléique (AGL)	100 mg
AO	Source d'acide oléique (AO)	100 mg

¹Pour les produits proposant des allégations sur ce tableau, les activités doivent être indiquées pour les constituants d'acides gras correspondants.

²Références: DPSNSO 2023; EFSA 2010a; EFSA 2010b; EFSA 2009; Simopolous 2007; IOM 2006; IOM 2002; Simopolous 1999.

Note : Les usages ci-dessus peuvent être combinés sur l'étiquette du produit (par ex., Aide à réduire les triglycérides et à maintenir la santé cardiovasculaire).

Mode(s) d'emploi

Énoncé non requis.

Règles et restrictions pour les associations

- Un usage ou fin n'est acceptable que si au moins un ingrédient médicinal/composante d'activité associé(e) avec cette allégation est présent(e) dans le produit à la dose ou au-dessus de la dose minimum quotidienne indiquée dans les tableaux 2 et 3.
- Les ingrédients médicinaux qui ne respectent pas la dose minimale quotidienne pour un usage ou fin seront considérés comme des ingrédients médicinaux complémentaires acceptables dans la formulation du produit.
- Tous les ingrédients médicinaux inclus dans cette monographie peuvent être associés selon les restrictions suivantes :
 - La dose quotidienne maximale d'un produit contenant des associations d'huiles ne doit pas dépasser 15,0 g par jour (DPSNSO 2023). Les doses quotidiennes maximales des ingrédients médicinaux individuels, indiquées dans le tableau 2, s'appliquent.
 - La dose quotidienne maximale d'une association AEP+ADH ou AEP+ADH+ADP dans un produit unique ne doit pas dépasser 5000 mg par jour pour les individus de 18 ans et plus (US FDA 2019; EFSA 2012).



Durée(s) d'utilisation

Énoncé non requis.

Mention(s) de risque

Précaution(s) et mise(s) en garde

Produits contenant de l'huile de chanvre, de l'huile d'argousier, de l'huile de krill, de l'huile de pépins de cassis et/ou de l'huile de calmar

Consultez un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant l'utilisation si vous êtes enceinte ou si vous allaitez.

Produits contenant de l'huile de poisson

Douleur causée par l'arthrite rhumatoïde

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

Équilibre de l'humeur

Consultez un praticien de soins de santé/fournisseur de soins de santé/professionnel de la santé/docteur/médecin avant l'utilisation si vous avez des troubles psychologiques tels que l'anxiété ou la dépression.

Contre-indications(s)

Énoncé non requis.

Réaction(s) indésirable(s) connue(s)

Produits contenant de l'huile de krill et/ou de l'huile de calmar

Cessez l'utilisation si une hypersensibilité/allergie se manifeste (SC 2017).

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*.

Produits contenant de l'huile de Schizochytrium, de l'huile de caméline, de l'huile de chanvre, de l'huile de foie de morue, de l'huile de poisson, de l'huile d'argousier, de l'huile de krill, de l'huile de lin, de l'huile de pépins de cassis, de l'huile de chia, de l'huile de phoque et/ou de l'huile de calmar sauf les produits encapsulés

Réfrigérer après l'ouverture (Wille et Gonus 1989).

Tous les produits (information pour l'industrie; pas pour l'étiquetage)

À être emballé dans un contenant hermétique, dans un endroit frais et à l'abri de la lumière (Ph.Eur. 2023; USP-NF 2023),

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.
- L'huile de foie de morue, l'huile de poisson, l'huile de krill, l'huile de phoque et l'huile de calmar sont des huiles marines et doivent respecter les exigences sur les contaminants dans les huiles marines du Guide de référence sur la qualité des produits de santé naturels de la DPSNSO pour les produits renfermant ces ingrédients.
- Pour tous les produits contenant un ou plusieurs ingrédients de cette monographie, les exigences sur la résistance des huiles à l'oxydation du Guide de référence sur la qualité des produits de santé naturels de la DPSNSO doit être respectée.
- Pour tous les produits ayant une ou plusieurs des activités indiquées dans la section des doses, une analyse doit être faite afin de confirmer l'activité/les activités en question.

Pour l'huile de poisson provenant des espèces de Gadidae

Pour les huiles de poisson incluant des espèces de Gadidae comme matière d'origine, le contenu en vitamine A et D doit être testé afin d'assurer que les doses maximales quotidiennes rencontrent la monographie des Suppléments de multivitamines/minéraux pour chaque groupe d'âge.

Huile de chanvre

Les produits renfermant de l'huile de chanvre ne doivent pas contenir plus de 10 parties par million de delta-9-Tétrahydrocannabinol (THC), ou des phytocannabinoïdes qui ont été isolés ou concentrés. La détermination de la concentration de THC doit tenir compte du potentiel de conversion de l'acide delta-9-tétrahydrocannabinolique (THCA) en THC. Les dérivés du chanvre

(par ex., huile de chanvre) doivent aussi être conformes au Règlement sur le chanvre industriel (RCI). Toutes les sources de chanvre relevant du RCI devraient appartenir à un cultivar approuvé, défini dans le RCI comme une variété de chanvre industriel figurant sur la Liste des cultivars approuvés, publiée par le gouvernement du Canada sur son site Web, avec ses modifications successives.

EXEMPLE D'INFO-PRODUIT :

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

Info-Produit	
Ingrédients médicinaux dans chaque capsule	
Huile de poisson (saumon de l'Atlantique, sardine, thon – en entier)	XX mg
Fournissant YY mg d'acide eicosapentaénoïque (AEP); ZZ mg d'acide docosahexaénoïque (ADH)	
Huile d'onagre (<i>Oenothera biennis</i> – graine)	XX mg
Huile d'olive (<i>Olea europaea</i> – fruit)	XX mg
Huile de germe de blé (<i>Triticum aestivum</i> – germe (graine))	XX mg
Fournissant YY mg d'acide linoléique	
Usages	
<ul style="list-style-type: none"> • Utilisé de pair avec un traitement conventionnel, aide à réduire chez les adultes la douleur causée par l'arthrite rhumatoïde. • Aide à promouvoir un bon équilibre de l'humeur. • Source d'acides gras essentiels pour le maintien d'une bonne santé. • Source d'acides gras oméga-6 pour le maintien d'une bonne santé. • Source d'acide linoléique (AL) pour le maintien d'une bonne santé. • Source d'antioxydants. • Source d'antioxydants qui aident à protéger les cellules contre les radicaux libres. 	
Mises en garde	
Si applicable¹ :	
Allergènes : allergène alimentaire, gluten (source de gluten), sulfites	
Contient de l'aspartame	
Consultez un praticien de soins de santé avant l'utilisation si vous avez des troubles psychologiques tels que l'anxiété ou la dépression ² .	
Consultez un praticien de soins de santé si les symptômes s'aggravent ³ .	
Mode d'emploi	
Adultes 18 ans et plus : • Prendre X capsule(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	

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

² Le qualificatif 'Si utilisé pour un bon équilibre de l'humeur:' peut être ajouté sur l'étiquette pour informer les consommateurs

³ Le qualificatif 'Pour la douleur causée par l'arthrite rhumatoïde : ' peut être ajouté sur l'étiquette pour informer les consommateurs.

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Annexe 1.

Densité des huiles fixes

Huiles fixes	Parties	Densité
Huile de bourrache	Graine	0,908 – 0,925 g/mL
Huile de lin bâtard	Graine	0,918 – 0,927 g/mL
Hemp seed oil	Graine	0,920 – 0,930 g/mL
Huile de canola	Graine	0,917 – 0,923 g/mL*
Huile de carthame	Graine	0,918 – 0,937 g/mL
Huile de noix de coco	Albumen (graine d'angiosperme)	0,913 – 0,919 g/mL
Huile de foie de morue	Foie	0,921 – 0,927 g/mL
Huile de graines de citrouille	Graine	0,901 – 0,924 g/mL
Huile de poisson	En entier	0,929 – 0,931 g/mL
Huile de tournesol	Graine	0,919 – 0,920 g/mL
Huile de fruit d'argousier	Fruit	0,913 – 0,919 g/mL
Huile de graines d'argousier	Graine	0,913 – 0,919 g/mL
Huile de krill	En entier	0,919 – 0,925 g/mL*
Huile de lin	Graine	0,928 – 0,935 g/mL
Huile d'onagre	Graine	0,918 – 0,930 g/mL
Huile d'olive	Chair	0,908 – 0,914 g/mL
Huile d'amandes douces	Graine	0,913 – 0,919 g/mL*
Huile de pépins de cassis	Graine	0,919 – 0,926 g/mL
Huile de graines de chia	Graine	0,922 – 0,927 g/mL
Huile de Schizochytrium (huile d'algue)	En entier	0,944 – 0,950 g/mL
Huile de phoque	Petit lard	0,921 – 0,927 g/mL*
Huile de calmar	En entier	0,953 – 0,959 g/mL*
Huile de germes de blé	Germe (graine)	0,922 – 0,937 g/mL
Huile de pépins de raisin	Graine	0,921 – 0,924 g/mL

*Lorsqu'une valeur unique a été trouvée dans les références, une variation de +/- 0,003 g/mL a été appliquée pour permettre une variabilité potentielle.

Au moins l'une des références suivantes a été utilisée pour appuyer les intervalles de densité :

Moovendhan 2021; Turck et al. 2021; Purnamayati et al. 2019; Uzunova et al. 2019; Delgado-et al. 2018; Petcu et al. 2016; Lee et al. 2014; Edwin et al. 2013; Firestone 2013; Manisha et Sharma 2011; Zhang et al. 2011; Alamu et al. 2010; Budavari 1996; Subrahmanyam et al. 1994; Kyte R.M. 1956.