Health Canada Santé Canada

PRODUIT DE SANTÉ NATUREL

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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.

Il existe plusieurs acides gras polyinsaturés *N*-3, mieux connus sous les noms d'acides gras omega-3/acides gras ω-3 (Ph.Eur. 2023). Cette monographie est spécifique à l'acide éicosapentaénoïque (C20:5 n-3; AEP) et à l'acide docosahexaénoïque (C22:6 n-3; ADH). Bien que d'autres acides gras oméga-3, y compris l'acide docosapentaénoïque (C22:5 n-3; ADP), puissent être naturellement présents dans les huiles marines et être inclus dans la teneur totale en acides gras oméga-3, les conditions d'utilisation recommandées et les allégations associées reposent sur la teneur en AEP et en ADH du produit.

Notes

- Cette monographie appuie uniquement les acides gras qui se trouvent naturellement dans l'huile de poisson avec à la fois de l'AEP et de l'ADH. Les huiles de poissons peuvent être concentrées mais pas enrichies avec des acides gras supplémentaires.
- Les parenthèses contiennent des éléments d'information additionnels (facultatifs) qui peuvent être inclus sur l'étiquette à la discrétion du demandeur.
- La barre oblique (/) indique que n'importe lequel des termes et/ou énoncés peut être sélectionné sur l'étiquette.

Date 25 septembre 2026

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[1]	Partie(s)
Huile de poisson	Huile de poisson	• Ammodytidae • Carangidae • Clupeidae • Engraulidae • Gadidae[2] • Osmeridae • Salmonidae • Scombridae	En entier

Références: Nom propre: BP 2023, Ph.Eur. 2023; Nom commun: BP 2023, Ph.Eur. 2023;

Informations d'origine: BP 2023, Ph.Eur. 2023, Froese et Pauly 2022.
[1]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 et Pauly 2022). Les noms communs des espèces et non pas les familles peuvent être listés sur l'étiquette.
[2]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.

Formes posologiques acceptables par groupe d'âge:

Enfants 1-2 ans: Les formes posologiques acceptables se limitent à l'émulsion/suspension et aux solutions/préparations liquides (Giacoia et al. 2008; EMA/CHMP 2006).
Enfants 3-5 ans: Les formes posologiques acceptables se limitent aux formes à croquer, à l'émulsion/suspension, aux poudres et aux solutions/préparations liquides (Giacoia et al. 2008; EMA/CHMP 2006).
Enfants 6-11 ans, Adolescents 12-17 ans, et Adultes 18 ans et plus: 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. Bien que les formes posologiques à libération retardée ne soient normalement pas appuyées par les monographies de la DPSNSO, cette monographie inclut 'Capsule, molle, enrobage entérique' qui est communément utilisée pour les produits d'huile marine.

Usage(s) ou fin(s)

Produits fournissant de 100 à 5 000 mg d'acide éicosapentaénoïque (AEP) et d'acide docosahexaénoïque (ADH)[1], par jour

- Source d'acides gras oméga-3 pour le maintien d'une bonne santé (EFSA 2012; Simopoulos 2007; Oh 2005; IOM 2002; Simopoulos 1999).
- Source d'acide éicosapentaénoïque (AEP) et d'acide docosahexaénoïque (ADH) pour le maintien d'une bonne santé (EFSA 2012; Simopoulos 2007; Oh 2005; IOM 2002; Simopoulos 1999).

Produits fournissant de 150 à 5 000 mg d'AEP et d'ADH[1], y compris au moins 100 mg d'ADH, par jour

- Aide à soutenir/maintenir la santé cognitive (EFSA 2012; van de Rest et al. 2008; Freund-Levi et al. 2006; Fontani et al. 2005a,b; Haag 2003; Morris et al. 2003; IOM 2002).
- Aide à soutenir/maintenir les fonctions cérébrales (EFSA 2012; van de Rest et al. 2008; Freund-Levi et al. 2006; Fontani et al. 2005a,b; Haag 2003; Morris et al. 2003; IOM 2002).

Produits pour les enfants jusqu'à 12 ans et fournissant de 200 à 2 000 mg d'AEP et d'ADH[1], y compris au moins 150 mg d'ADH, par jour

Aide à soutenir/maintenir le développement (sain) du cerveau/(et), des yeux/(et) des nerfs chez les enfants jusqu'à 12 ans (Marszalek et Lodish 2005; Haag 2003; IOM 2002; Giedd et al. 1999; Mills 1999).

Produits fournissant de 200 à 5 000 mg d'AEP et d'ADH[1], par jour

- Aide à soutenir/maintenir la/une santé cardiovasculaire/du cœur (normale) (EFSA 2012; Oh 2005; Wang et al. 2004; Leaf et al. 2003; Kris-Etherton et al. 2002).
- Aide à soutenir/maintenir une/les fonction(s) cardiovasculaire(s)/du cœur (normale(s)) (EFSA 2012; Oh 2005; Wang et al. 2004; Leaf et al. 2003; Kris-Etherton et al. 2002).

Produits fournissant de 1 000 à 5 000 mg d'AEP et d'ADH[1], par jour

- Aide à réduire (les taux de)/(les) triglycérides/triacyglycérols (sanguins) (EFSA 2012; Oh 2005; Balk et al. 2004; Hooper et al. 2004; Nilsen et al. 2001; Sirtori et al. 1998).
- Aide à soutenir/maintenir les taux normaux de triglycérides/triacyglycérols (sanguins) (EFSA 2012; Oh 2005; Balk et al. 2004; Hooper et al. 2004; Wang et al. 2004; Leaf et al. 2003; Kris-Etherton et al. 2002; Nilsen et al. 2001; Sirtori et al. 1998).

Produits pour les adultes et fournissant de 2 800 à 5 000 mg d'AEP et d'ADH[1], par jour et présentant un ratio AEP:ADH entre 0,5:1 et 2:1

Utilisé de pair avec un traitement conventionnel, aide à réduire la douleur causée par l'arthrite rhumatoïde chez les adultes (EFSA 2012; Volker et al. 2000; Sköldstam et al. 1992).

Produits fournissant de 1 500 à 5 000 mg d'AEP et d'ADH[1], y compris au moins 1 000 mg d'AEP, par jour

Aide à promouvoir un bon équilibre de l'humeur (EFSA 2012; Nemets et al. 2006; Sontrop et Campbell 2006; Fontani et al. 2005a,b; Zanarini et Frankenburg 2003; Peet et Horrobin 2002; Stoll et al. 1999).

Notes

- [1]L'AEP et l'ADH peuvent être déclarés en tant qu'acides gras oméga-3 sur le formulaire de DLMM.
- 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).

Dose(s)

Sous-population(s)

Tel que spécifié ci-dessous.

Quantité(s)

Méthode de préparation: Huile fixe normalisée

En plus de la quantité d'huile de poisson, l'activité doit être fournie. L'activité peut soit être exprimée en quantité (milligrammes) et/ou en pourcentage (%) d'AEP et d'ADH (% poids/poids) par rapport à la quantité totale d'huile de poisson, ou remplacée par le sous-ingrédient, acides gras oméga-3, sur le formulaire de DLMM.

Si l'activité est déclarée sous la dénomination **« acides gras oméga-3 »**, le titulaire de licence doit s'assurer que les quantités minimales d'AEP et d'ADH requises pour appuyer les allégations sélectionnées sont respectées. La documentation démontrant la teneur en AEP et en ADH doit être conservée et fournie sur demande.

Les acides gras oméga-3 de l'huile de poisson peuvent comprendre l'AEP, l'ADH et l'ADP.

- Si la teneur est indiquée comme « acides gras oméga-3 » sur le formulaire de DLMM, l'étiquette peut également présenter les quantités d'AEP et d'ADH à titre d'information supplémentaire.
- À l'inverse, si l'AEP et l'ADH sont indiqués sur le formulaire de DLMM, l'étiquette peut également présenter la teneur totale en acides gras oméga-3 à titre d'information supplémentaire.
- Lorsque l'ADP est présent, il peut être indiqué comme information supplémentaire sur l'étiquette commercialisée.

Tableau 2. Doses quotidiennes d'acide éicosapentaénoïque (AEP) et d'acide docosahexaénoïque (ADH) dans l'huile de poisson.

Sous-population(s)		AEP + ADH[1] (mg/jour)	
		Minimum[2]	Maximum[3]
Enfants	1 à 8 ans	100	1 500

	9 à 11 ans	100	2 000
Adolescents	12 à 13 ans	100	2 000
	14 à 17 ans	100	2 500
Adultes	18 ans et plus	100	5 000

[1]L'AEP et l'ADH peuvent être déclarés en tant qu'acides gras oméga-3 sur le formulaire de DLMM. Les doses quotidiennes minimales s'appliquent également au sous-ingrédient « acides gras oméga-3 » comme seuil minimal; toutefois, la teneur en ADP doit être prise en compte. Compte tenu de la présence possible d'ADP, aucune dose quotidienne maximale n'est fixée, afin de permettre au produit d'atteindre la quantité maximale d'AEP + ADP.
[2]Certaines restrictions aux doses minimales peuvent s'appliquer selon la section des usage(s) ou fin(s) ci- dessus.
[3]La dose maximale adulte d'AEP + ADH est appuyée par US FDA 2019 et EFSA 2012. Les doses maximales pour enfants et adolescents, sont calculées à partir d'une fraction de la dose adulte, dépendent du poids corporel et de l'apport calorique.

Mode(s) d'emploi

Énoncé non requis.

Durée(s) d'utilisation

Énoncé non requis.

Mentions de risque

Précaution(s) et mise(s) en garde

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)

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*.

Tous les produits, sauf ceux encapsulés

Réfrigérer après ouverture (Wille et Gonus 1989).

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

À être emballé dans un contenant hermétique 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.
- Les niveaux de peroxyde, d'anisidine et les niveaux totaux d'oxydation de l'huile de poisson et des dérivés d'acides gras oméga-3 provenant de l'huile de poisson doivent respecter les normes établies par l'Association of Analytical Community (AOAC) et/ou les méthodes analytiques des pharmacopées. Ces spécifications assureront la résistance à l'oxydation de l'huile de poisson et des acides gras oméga-3 provenant de l'huile de poisson (SC 2015). Le niveau maximal de l'indice de peroxyde (IP) doit être 5 mEq/kg, le niveau maximal de l'indice d'anisidine (IA) doit être 20 tandis que le niveau maximal du total d'oxydation doit être 26 (calculé selon la formule : 2 X IP + IA).
- Les dioxines polychlorodibenzo-para-dioxines (PCDD) et polychlorodibenzofuranes (PCDF), les polychlorobiphényles de type dioxine (PCBTD) et les polychlorobiphényles (PCB) sont des contaminants présents dans les huiles marines. Des analyses pour détecter ces contaminants sont obligatoires. Tel que mentionné dans le Guide de référence sur la

qualité des produits de santé naturels, il convient d'utiliser des méthodes d'analyse appropriées, comme la méthode n° 1613 (révision B) pour les PCDD et les PCDF et la méthode no 1668B pour les congénères de biphényles chlorés de l'EPA. Pour plus d'information, il est conseillé aux titulaires d'une licence de mise en marché de consulter les documents de la Commission européenne sur les dioxines et les PCB de type dioxine dans les huiles marines. Consultez le Guide de référence sur la qualité des produits de santé naturels pour obtenir plus d'informations sur les limites acceptables de dioxines et de PCB de type dioxine.

- 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.

EXEMPLE D'INFO-PRODUIT :

Veuillez consulter la ligne directrice, Étiquetage des produits de santé naturels pour plus de détails.

Info-Produit
Ingrédient médicinal dans chaque capsule Huile de poisson (saumon de l'Atlantique; sardine, thon - en entier) XX mg Fournissant YY mg d'acide éicosapentaénoïque (AEP); ZZ mg d'acide docosahexaénoïque (ADH)
Usages • 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.
Mises en garde
Si applicable[1] : **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.
Consultez un praticien de soins de santé si les symptômes s'aggravent[2].
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 'Pour la douleur causée par l'arthrite rhumatoïde :' peut être ajouté sur l'étiquette pour informer les consommateurs.

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Historique des versions

Date de publication	Type de mise à jour	Résumé des principales mises à jour (à partir de septembre 2026)
2026-09-25	Mises à jour mineures	• Clarification de l'énoncé introductif afin de reconnaître que l'ADP peut également être présent dans les huiles marines • Ajout du sous-ingrédient, acides gras oméga-3, pouvant être utilisé sur le formulaire de DLMM afin d'offrir une plus grande flexibilité relativement aux variations de la teneur en AEP et en ADH, pourvu que le titulaire de licence s'assure que la formulation du produit respecte les exigences de la monographie relatives à l'AEP et à l'ADH. La documentation démontrant la teneur en AEP et en ADH doit être conservée et fournie sur demande • Ajout de notes dans les sections « Utilisation ou fins recommandées » et « Quantité » concernant l'utilisation des acides gras oméga-3 comme information sur l'activité, en remplacement de déclarations distinctes de la

Date de publication	Type de mise à jour	Résumé des principales mises à jour (à partir de septembre 2026)
		teneur en AEP et en ADH
2025-12-25	Mises à jour mineures	–
2025-09-26	Mises à jour mineures	–
2024-03-28	Mises à jour moyennes (avec consultation)	–
2018-09-25	Validation	–
2017-07-18	Mises à jour mineures	–
2013-07-10	Mises à jour mineures	–
2012-07-04	Mises à jour mineures	–
2009-03-27	Mises à jour mineures	–
2008-01-10	Mises à jour mineures	–
2006-08-08	Version initiale	–