Health Canada Santé Canada

NATURAL HEALTH PRODUCT

COD LIVER OIL

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.
- The use(s) or purpose(s) statements in this monograph are based on the efficacy of vitamin A, vitamin D, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) that are present in cod liver oil. The references used to support these statements refer to the efficacy of these individual constituents and are not specific to cod liver oil.

Date September 25, 2018

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Organism group(s)	Part(s)
Cod liver oil	• Cod Liver Oil • Lecoris Aselli Oleum	• Melanogrammus aeglefinus • Arctogadus glacialis • Gadus macrocephalus • Gadus morhua • Gadus ogac • Pollachius virens	Liver

References: Proper name: Ph.Eur. 2012, USP 35 2012; Common names: Ph.Eur. 2012, USP 35 2012; Source information: BP 2012, Ph.Eur. 2012, USP 35 2012.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms by age group:

Infants 0 - 12 months, and Children 1-2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006). **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/ suspension, powders and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006). **Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:** The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Products providing daily doses of vitamin A at or above the Recommended Dietary Allowance (RDA) or Adequate Intake (AI) (adjusted for the life stage groups)

- Helps to prevent vitamin A deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).

Products providing daily doses of vitamin D at or above the Recommended Dietary Allowance (RDA) or Adequate Intake (AI) (adjusted for the life stage groups)

- Helps to prevent vitamin D deficiency (IOM 2011, 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1997).

Products providing 138-3,000 µg retinol activity equivalents (RAE) (µg vitamin A/all-trans retinol (palmitate)), per day

- Helps to maintain eyesight, skin membranes and immune function (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- Helps in the development and maintenance of night vision (IOM 2006; Shils et al. 2006; Groff and Gropper 2000).
- Source of vitamin A, a factor in the maintenance of good health (IOM 2006)

Products providing 1.15-25 µg vitamin D_3/cholecalciferol, per day

- Helps in the development and maintenance of bones and teeth (IOM 2011; Shils et al. 2006).
- Helps in the absorption and use of calcium and phosphorus (IOM 2011; Shils et al. 2006; Groff and Gropper 2000).
- Source of vitamin D, a factor in the maintenance of good health (IOM 2011).

Products providing 100-1,360 mg eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA), per day

- Source of omega-3 fatty acids for the maintenance of good health (Simopoulos 2007; Oh 2005; IOM 2002; Simopoulos 1999)
- Source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for the maintenance of good health (Simopoulos 2007; Oh 2005; IOM 2002; Simopoulos 1999)

Products providing 100-1,360 mg EPA + DHA including at least 100 mg DHA, per day

- Helps support cognitive health and/or brain function (van de Rest et al. 2008; Freund-Levi et al. 2006; Fontani et al. 2005a,b; Haag 2003; Morris et al. 2003; IOM 2002).

Products providing 150-1,360 mg EPA + DHA including at least 150 mg DHA, per day (maximum doses of EPA + DHA in Table 5 below will apply)

- Helps support the development of the brain, eyes and nerves in children up to 12 years of age (Agostini 2008; Helland et al. 2008; Ryan and Nelson 2008; Marszalek and Lodish 2005; Haag 2003; IOM 2002; Giedd et al. 1999; Mills 1999).

The following combined use(s) or purpose(s) is/are also acceptable:

- Helps to maintain eyesight, skin membranes, immune function, and bones and teeth.
- Source of vitamin A, omega-3 fatty acids, eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and Vitamin D, which are factors in the maintenance of good health.

Vitamin A and Vitamin D at or above the RDA or AI

- Helps to prevent vitamin A and D deficiency

Note
Refer to Appendix IV of the NNHPD Multivitamin/mineral Supplements monograph for the RDA and AI of Vitamin A and Vitamin D.

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Method of preparation: Standardized fixed oil

Note
The potencies of vitamin A, vitamin D_3 and EPA + DHA must be indicated on the PLA and label, in addition to the dose of Cod liver oil.

Table 2. Daily dose for cod liver oil[1]

Subpopulation(s)		Cod liver oil			
		Minimum[2]		Maximum[4]	
		(ml/day)[5]	(g/day)	(ml/day)	(g/day)
Infants	0-12 month(s)	0.83	0.77	0.87	0.80
Children	1-3 year(s)	0.83	0.77	0.87	0.80
	4-8 years	0.83	0.77	1.3	1.2
	9-11 years	0.83	0.77	2.4	2.2
Adolescents	12-13 years	0.83	0.77	2.4	2.2
	14-17 years	0.83	0.77	4.0	3.7
Adults[3]	18 years	0.83	0.77	4.0	3.7
	19 years and older	0.83	0.77	4.3	4.0

[1] BP 2012, Ph.Eur. 2012 or USP 35 2012 grade Cod liver oil must be used to ensure that potencies of vitamin A, vitamin D_3, and EPA + DHA listed in Tables 3, 4 and 5 are met.
[2] The minimum dose of Cod liver oil is based on the minimum quantities of EPA + DHA required for efficacy.
[3] Includes pregnant and breastfeeding women.
[4] For all subpopulations, the maximum dose is based on the quantity of Cod liver oil providing the maximum daily amount of vitamin A, in µg RAE, according to the UL (IOM 2006).
[5] Based on the specific gravity of Cod liver oil (USP 35 2012)

Potencies

Table 3. Potency[1] for vitamin A in cod liver oil

Subpopulation(s)		Vitamin A (µg RAE/day)	
		Minimum[2]	Maximum[3]
Infants	0-12 month(s)	138	600
Children	1-3 year(s)	138	600
	4-8 years	138	900
	9-11 years	138	1,700
Adolescents	12-13 years	138	1,700
	14-17 years	138	2,800

Adults[4]	18 years	138	2,800
	19 years and older	138	3,000

[1] References for the potency of vitamin A are: BP 2012, Ph.Eur. 2012, and Tischer 1938.
[2] Calculated as the minimum amount of vitamin A available in 0.77 g Cod liver oil, which is the based on the minimum quantities of EPA + DHA required for efficacy.
[3] Maximum potency based on the UL (IOM 2006).
[4] Includes pregnant and breastfeeding women.

Table 4. Potency[1] for vitamin D_3/cholecalciferol in cod liver oil

Subpopulation(s)		Vitamin D_3 (µg/day)	
		Minimum[2]	Maximum[3]
Infants	0-12 month(s)	1.15	5.00
Children	1-3 year(s)	1.15	5.00
	4-8 years	1.15	7.50
	9-11 years	1.15	14.06
Adolescents	12-13 years	1.15	14.06
	14-17 years	1.15	23.12
Adults[4]	18 years	1.15	23.12
	19 years and older	1.15	25.00

[1] References for the potency of Vitamin D3 are: BP 2012, Ph.Eur. 2012, and Green 1951.
[2] Based on the minimum amount of vitamin D3 available in 0.77 g Cod liver oil, and supported by the RDA and AI for.vitamin D (IOM 2011, 2006).
[3] For all subpopulations, the maximum potencies are based on the amount of vitamin D3 available in the quantity of Cod liver oil which provides the maximum daily amount of vitamin A, in µg RAE, according to the UL (IOM 2006).
[4] Includes pregnant and breastfeeding women.

Table 5. Potency[1] for EPA + DHA in cod liver oil

Subpopulation(s)		EPA + DHA (mg/day)	
		Minimum[2]	Maximum[3]
Infants[4]	0-12 month(s)	100	272
Children	1-3 year(s)	100	272
	4-8 years	100	408
	9-11 years	100	765
Adolescents	12-13 years	100	765
	14-17 years	100	1,258
Adults[5]	18 years	100	1,258
	19 years and older	100	1,360

[1] References for the potency of EPA + DHA are: BP 2012 and Ph.Eur. 2012.
[2] Restrictions to minimum potency may apply according to Use(s) or Purpose(s) section above.

[3] For all subpopulations, the maximum potencies are based on the amount of EPA + DHA available in the quantity of Cod liver oil which provides the maximum daily amount of vitamin A, in µg RAE, according to the UL (IOM 2006).
[4] USP 35 2012; Rajakumar and Thomas 2005; Stene et al 2003; Linday et al. 2002.
[5] Includes pregnant and breastfeeding women.

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

No statement required.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage condition(s)

All products

Store in airtight container, protected from light (Ph.Eur. 2012; USP 35 2012).

All products, except those encapsulated

Refrigerate after opening (Wille and Gonus 1989).

Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.
- Peroxide, anisidine, and totox values of cod liver oil and omega-3 fatty acids derived from cod liver oil must be in accordance with the methods set out by the Association of Analytical Communities (AOAC) and/or Pharmacopoeial analytical methods. These specifications are necessary to ensure the oxidative stability of the cod liver oil and the omega-3 fatty acids from cod liver oil (HC 2007). The maximum peroxide value (PV) must be 5 mEq/kg, the maximum anisidine value (AV) must be 20 while the maximum Totox value must be 26 (calculated as 2 X PV + AV).
- The dioxins, polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs); the dioxin-like polychlorinated biphenyls (DL PCBs); and the polychlorinated biphenyls (PCBs) are contaminants in marine oils. Testing for these contaminants is required. Testing should be performed using appropriate analytical methods, such as method No. 1613 revision B of the Environmental Protection Agency for PCDDs and PCDFs and method No. 1668B of the Environmental Protection Agency for chlorinated biphenyl congeners (Ph. Eur: EPA 2008; EPA 1994). Licence holders are advised to consult the Commission of the European Communities documents on dioxins and dioxin-like PCB contaminants in marine oil for further information (EU 2006a.b; EU 2001). Refer to Section 3.3.8 of the Quality of Natural Health Products Guide for more information on the acceptable limits of dioxins and dioxin-like PCBs.

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