

NÉEVODHA[®] Gelcaps Rx

Description

NeevoDHA[®] is an opaque blue gelatin capsule. The product contains:

Each Blue gelatin capsule contains:

Dietary Ingredients:

L-Methylfolate Calcium (as Metafolin [®]) [§]	1.13mg [†]
Calcium (tricalcium phosphate)	75mg
Elemental Iron (ferrous fumarate)	27mg
Vitamin C (ascorbic acid)	40mg
Vitamin E (D-alpha-tocopherol)	30IU
Vitamin B ₆ (pyridoxine HCl)	25mg
Vitamin B ₉ (folic acid)	400mcg
Vitamin B ₁₂ (methylcobalamin)	1mg
Docosahexaenoic Acid (DHA)	250mg [‡]

[§]CAS#151533-22-1

[†]1.13mg L-Methylfolate Calcium is the molar equivalent of 1.0mg folic acid.

[‡]Docosahexaenoic acid (DHA) from an algal source.

CAS# 151533-22-1 is the registry of the absolute stereochemistry of L-methylfolate calcium

Inactive Ingredients:

Gelatin, tricalcium phosphate, glycerine, beeswax, soy lecithin, soybean oil, titanium dioxide, ethyl vanillin, FD&C blue #1, FD&C red #40, white ink (ammonium hydroxide, isopropyl alcohol, N-butyl alcohol, propylene glycol, shellac glaze in SD-45, simethicone, titanium dioxide).

Metafolin[®] (L-methylfolate calcium) is a substantially diastereoisomerically pure source of L-methylfolate containing not more than 1% D-methylfolate which results in not more than 0.011 milligrams of D-methylfolate in NeevoDHA[®].

D-methylfolate or 6(R)-5-methyltetrahydrofolate [6(R)-5-MTHF] is the other diastereoisomer of folate. Studies administering doses of 2.5 mg per day or higher resulted in plasma protein binding of D-methylfolate higher than L-methylfolate causing a significantly higher renal clearance of L-methylfolate when compared to D-methylfolate.¹ Further, D-methylfolate is found to be stored in tissues in the body, mainly in the liver. D-methylfolate is not metabolized by the body and has been hypothesized to inhibit regulatory enzymes related to folate and homocysteine metabolism and reduces the bioavailability of L-methylfolate.²

Indications

NeevoDHA[®] is a multivitamin/multimineral nutritional supplement for women who require increased vitamin, mineral and essential fatty acid concentrations throughout pregnancy and the postnatal period for both lactating and non-lactating mothers. It can be used prior to conception to improve nutritional status.

Contraindications

Known hypersensitivity to any of the components in this product is a contraindication.

Warnings

Ingestion of more than 3 grams per day of omega-3 fatty acids has been shown to have potential antithrombotic effects, including bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Precautions

Folates, when administered as a single agent in doses above 0.1mg daily, may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

MERCK EXHIBIT 2259

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Adverse Reactions

While allergic sensitization has been reported following both oral and parenteral administration of folic acid, allergic sensitization has not been reported with the use of Metafolin®.

Patient Information

NeevoDHA® is certified kosher by Triangle K and Associates.

Dosage and Administration

Usual adult dose is 1(one) gelatin capsule daily or as directed by your physician.

How Supplied

NeevoDHA® are blue, soft gelatin capsules, imprinted with "NeevoDHA" on one side in white ink. Commercial product is supplied in bottles of 30 gelatin capsules. Sample product is supplied in bottles of 4 gelatin capsules.

Commercial Product (30 gelatin capsules)	NDC 0525-2030-30	Rx only
Sample Product (4 gelatin capsules)	NDC 0525-2030-04	Professional Samples – Not for sale.

Storage

Store at controlled room temperature 15°C to 30°C (59°F to 86°F) (See USP). Protect from light and moisture. Dispense commercial product in original container. Dispense sample product in original container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Patents

Some or all of the following patents may apply:

U.S. Patent No. 6,207,651	U.S. Patent No. 5,563,126
U.S. Patent No. 6,254,904	U.S. Patent No. 5,795,873
U.S. Patent No. 6,297,224	U.S. Patent No. 5,997,915
U.S. Patent No. 6,528,496	U.S. Patent No. 6,011,040

and other pending patent applications.

1. Stroes E, van Faassen E, Circ Res 2000; 86:1129-34.
2. Willems FF et al. Br J Pharmacol.2004;141(5):825-30.

Metafolin® is a registered trademark of Merck KGaA, Darmstadt, Germany.

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PAMLAB, L.L.C. Covington, LA 70433

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Accucaps Industries Ltd., Windsor, Ontario N9C 3R5

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