

NÉEVO®DHA

Neevo®DHA is a prescription pre & post natal medical food for the distinct nutritional requirements of preconception and pregnant women who require increased vitamin¹, mineral and DHA^{2,3} concentrations throughout pregnancy and the postnatal lactating period.

Description

Neevo®DHA is an opaque blue gelatin capsule. The product contains:

Each Blue gelatin capsule contains:

Dietary Ingredients:

L-Methylfolate (6(S)-5-MTHF) (Metafolin®)	1mg
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

Capsule Ingredients:

DHA (docosahexaenoic acid from an algal source), gelatin, tricalcium phosphate, glycerine, beeswax, ferrous fumarate, ascorbic acid, lecithin, pyridoxine HCl, D alpha tocopherol, soybean oil, L-methylfolate, titanium dioxide, methylcobalamin, folic acid, ethyl vanillin, FD&C blue #1, FD&C red #40, food grade white ink (ammonium hydroxide, isopropyl alcohol, N-butyl alcohol, propylene glycol, shellac glaze in SD-45, simethicone, titanium dioxide).

Indication and Usage

Neevo®DHA is indicated for the distinct nutritional requirements of preconception and pregnant women who require increased vitamin¹, mineral and essential fatty acid^{2,3} concentrations throughout pregnancy and the postnatal period for both lactating^{3,4,5} and non-lactating mothers, with particular emphasis for those individuals who have or are at risk for the folate 677C→T polymorphism^{6,7,8} and/or women who are associated with intermediate- to higher- risk pregnancies^{9,10,11}. 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.

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®.

Drug Interactions

Pyridoxine hydrochloride should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine hydrochloride. However, pyridoxine hydrochloride may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. While the concurrent use of phenytoin and folic acid may result in decreased phenytoin effectiveness, no such decreased effectiveness has been reported with the use of

Metafolin®. Capecitabine (Xeloda®) toxicity may increase with the addition of leucovorin (5-formyltetrahydrofolate) (folate).

Pharmacology

L-methylfolate

L-methylfolate or 6(S)-5-methyltetrahydrofolate [6(S)-5-MTHF], is the primary biologically active isomer of folate¹² and the form of folate in circulation¹³. It is also the form which is transported across membranes into peripheral tissues¹⁴, particularly across the blood brain barrier¹⁵. In the cell, 6(S)-5-MTHF is used in the methylation of homocysteine to form methionine and tetrahydrofolate (THF).^{6,9} THF is the immediate acceptor of one carbon units for the synthesis of thymidine-DNA, purines (RNA and DNA) and methionine^{6,9}. Folic acid, the synthetic form of folate, must undergo enzymatic reduction by methylenetetrahydrofolate reductase (MTHFR) to become biologically active⁶. Genetic mutations of MTHFR¹⁰ result in a cell's inability to convert folic acid to 6(S)-5-MTHF⁶.

Docosahexaenoic acid

docosahexaenoic acid or DHA, a long-chain polyunsaturated omega-3 fatty acid (C22:6n-3). DHA is an indispensable component of all cell membranes and is incorporated in high concentrations in the membrane phospholipids of brain and retina¹⁶. The DHA in Neevo®DHA comes from a vegetarian source (algae), not from fish, grown in an FDA-inspected facility¹⁷.

Patient Information

Neevo®DHA is a medical food for use only under the direction and supervision of a licensed physician. Neevo®DHA 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

Neevo®DHA are blue, soft gelatin capsules, imprinted with "NeevoDHA" on one side in white ink. Commercial product (00525-2030-30) is supplied in bottles of 30 capsules. Sample product (00525-2030-04) is supplied in bottles of 4 capsules.

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.

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

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. 4,940,658	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.

References

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- ¹⁷ Referenced by Martek Biosciences Corporation, Columbia, Maryland USA

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