

NEEVODHA®

DESCRIPTION

NeevoDHA® is a medical food dispensed by prescription for use only under medical supervision for the dietary management of impaired metabolic processes in women under a doctor's care who face high to intermediate risk pregnancies and are unable to fully metabolize or absorb folic acid. Use under medical supervision.

Each opaque blue gelatin capsule contains:

Algidha™ proprietary blend*	687mg*
Elemental calcium (tricalcium phosphate)	75mg
Vitamin C (ascorbic acid)	40mg
Elemental iron (ferrous fumarate)	27mg
Vitamin B6 (pyridoxine HCl)	25mg
Vitamin E (d-alpha-tocopherol)	30IU
L methylfolate Calcium (as Metafolin®) CAS# 151533-22-1	1.13mg
Vitamin B12 (methylcobalamin)	1mg
Vitamin B9 (folic acid)	400 mcg

* Algidha™ is a proprietary blend containing algal oil and soy lecithin.

Ingredients:

Algidha™ (algal oil and soy lecithin), gelatin, tricalcium phosphate, glycerin, beeswax, ferrous fumarate, ascorbic acid, pyridoxine HCl, d-alpha tocopherol, L-methylfolate calcium, titanium dioxide (color), 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). **Contains Soy**

Medical foods are intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.¹ This product is not an Orange Book product.

NeevoDHA® is a medical food dispensed by prescription.

CLINICAL PHARMACOLOGY

NeevoDHA® is a medical food, which consists of a proprietary blend of biologically active folate, vitamins, minerals and long-chain polyunsaturated fatty acids, derived from food sources.

INDICATION AND USAGE

NeevoDHA® gelatin capsules are for the specific dietary management of impaired metabolic processes in those women with distinct nutritional requirements for any of the following conditions: hyperhomocysteinemia during pregnancy^{2,3,4,5}; high risk recurrent pregnancy loss^{2,5}; risk of anemia due to impaired folic acid absorption^{6,7,8,9,10,11}; and impaired metabolism due to 677C-T mutations in the methylenetetrahydrofolate reductase gene^{11,12,13}.

CONTRAINDICATIONS

NeevoDHA® is contraindicated in patients with known hypersensitivity to any of the components in this product.

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

General:

Folic acid, when administered in daily doses above 0.1mg, may obscure the detection of B₁₂ deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B₁₂ deficiency, including pernicious anemia, while not addressing the neurological manifestations). L-methylfolate calcium may be less likely than folic acid to mask vitamin B₁₂ deficiency^{14, 15}. Folate therapy alone is inadequate for the treatment of a B₁₂ deficiency.

Patient Information:

NeevoDHA[®] is a medical food¹ for use under medical supervision and direction.

NeevoDHA[®] is a medical food dispensed by prescription

NeevoDHA[®] is certified kosher by Triangle K and Associates.

Contains Soy

Interaction with Drugs:

Before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist. No decrease in effectiveness of drugs has been reported with the use of NeevoDHA[®].

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate calcium.¹⁷ Acne, skin reactions, allergic reactions, photosensitivity, nausea, vomiting, abdominal pain, loss of appetite, increased liver function test results, paresthesia, somnolence, nausea and headaches have been reported with pyridoxine.¹⁸ Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with methylcobalamin.¹⁶

Dosage and Administration

The usual adult dose is one gelatin capsule daily or as directed under medical supervision.

How Supplied

NeevoDHA[®] is a medical food dispensed by prescription.

NeevoDHA[®] is available as an opaque blue gelatin capsule with "Neevo DHA" imprinted on one side in white ink.

Commercial Product (30 gelatin capsules)	0525-0621-30*	Use under medical/physician supervision.
Sample Product-Bottle (4 gelatin capsules)	0525-0621-04*	Professional samples-not for sale

*Pamlab, L.L.C. does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirements of pharmacy and health insurance computer systems.

Storage

Store at controlled room temperature 15°C to 30°C (59°F to 86°F) (See USP). Protect from light and moisture.

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. 5,407,957	U.S. Patent No. 6,441,168B1
U.S. Patent No. 5,492,938	U.S. Patent No. 6,451,360
U.S. Patent No. 5,563,126	U.S. Patent No. 6,673,381
U.S. Patent No. 5,795,873	U.S. Patent No. 7,163,811
U.S. Patent No. 6,011,040	U.S. Patent No. 7,172,778
U.S. Patent No. 6,254,904	U.S. Patent No. 7,674,490
U.S. Patent No. 6,297,224	and other pending patent applications

REFERENCES

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Distributed By

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

Revised 7/11