

NeevoDHA™

NATURE'S ACTIVE FOLATE FOR PRENATAL CARE

NEEVODHA™ capsule 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 B6 (pyridoxine as pyridoxine HCl).....	25mg
Vitamin B9 (folic acid).....	400mcg
Vitamin B12 (methylcobalamin).....	1mg
Docosahexaenoic Acid (DHA).....	250mg**

*1.13mg L-Methylfolate (calculated as L-methyltetrahydrofolic acid) is the molar equivalent of 1.0mg folic acid.

**Docosahexaenoic acid (DHA) from an algal source.

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™.

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.

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.



NeevoDHA™ is gluten-free, lactose-free and yeast-free.

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 NDC 0525-2030-30 is supplied in bottles of 30 capsules. Sample product- NDC 0525-2030-04 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)

NDC 0525-2030-30 Rx only

Sample Product (4 gelatin capsules)

NDC 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.

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

Distributed By

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



Manufactured by

Accucaps Industries Ltd., Windsor, Ontario N9C 3R5

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References

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2. Data on File <http://clinicaltrials.gov/ct2/show/NCT01062958>
3. CitraNatal 90DHA Package Insert. San Antonio, TX, Mission Pharmacal Company, February 2009. CitraNatal is the registered trademark of Mission Pharmacal company.
4. Neevo® Package Insert. Covington, LA Pamlab, L.L.C. 2009
5. NeevoDHA™ Package Insert. Covington, LA Pamlab, L.L.C. 2009
6. PrenateDHA Package Insert. Atlanta, GA, Sciele Pharma, Inc. August, 2008. PrenateDHA is the registered trademark of Sciele Pharma, Inc.
7. Prenate Elite Package Insert. Atlanta, GA, Sciele Pharma, Inc. August, 2008. Prenate Elite is the registered trademark of Sciele Pharma, Inc.
8. Prenexa Package Insert. Minneapolis, MN, Upsher-Smith Laboratories, Inc. January, 2010. Prenexa is the registered trademark of Upsher-Smith Laboratories Inc.
9. Tandem is the registered trademark of U.S. Pharmaceutical Corporation.
10. PrimaCare One is the registered trademark of Drugtech Corporation.
11. Duet is the registered trademark of Xanodyne Pharmaceuticals, Inc.
12. Gesticare is the registered trademark of Azur Pharma International II Limited Inc.
13. Citrinatal is the registered trademark of Mission Pharmacal Company
14. New World Encyclopedia Website. <http://www.newworldencyclopedia.org/entry/anemia>
15. Source: Blinded telephone poll of 300 OB offices during August, 2009. Responses taken from physicians, PA's, RN's and Midwives who are now pregnant in these offices.

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