

C-NATE DHA- omega-3 fatty acids, icosapent, doconexent, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, folic acid, cholecalciferol, ascorbic acid, .alpha.-tocopherol, d-, cupric sulfate, zinc oxide, ferrous fumarate and magnesium oxide capsule, gelatin coated

Centurion Labs, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

C-Nate DHA

PRENATAL / MULTIVITAMIN

Rev. 10/12

Rx ONLY

Description:

Each Softgel Contains:

Omega-3 Fatty Acids (DHA-EPA)	200mg
Vitamin B ₁ (Thiamine Mononitrate)	3 mg
Vitamin B ₂ (Riboflavin)	3 mg
Vitamin B6 (Pyridoxine HCL)	20 mg
Vitamin B ₁₂ (Cyanocobalamin)	15 mcg
Folic Acid	1 mg
Vitamin D ₃ (Cholecalciferol)	400 IU
Vitamin C (Ascorbic Acid)	100 mg
Vitamin E (d-alpha tocopherol)	30 IU
Copper (Cupric Sulfate)	1 mg
Zinc (Zinc Oxide)	20 mg
Iron (Fumerate)	28 mg
Magnesium	30 mg

INACTIVE INGREDIENTS: Gelatin, Glycerol, beeswax yellow, lecithin, water-purified and colorant.

INDICATIONS AND USAGE: C-NATE DHA is a prescription multivitamin/multimineral indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers.

CONTRAINDICATIONS: C-NATE DHA should not be used by patients with known history of hypersensitivity to any of the listed ingredients.

PRECAUTIONS: Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient. Folic Acid in doses above 0.1 mg daily may

obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

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.

PEDIATRIC USE: Safety and effectiveness in pediatric patients has not been established.

GERIATRIC USE: No clinical studies have been performed in patients over 65 to determine whether older persons respond differently from younger persons. Physicians should consider that elderly person may have decreased hepatic, renal, or cardiac function.

DRUG INTERACTIONS: C-NATE DHA softgels are not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine.

ADVERSE REACTIONS: Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels. Iron, even at the usual recommended levels, has been associated with gastrointestinal intolerance in some patients.

DOSAGE AND ADMINISTRATION: Usual adult dose: one softgel daily or as prescribed by your doctor.

HOW SUPPLIED: C-NATE DHA is available as a Amato colored softgel, imprinted PRE 01. Available in 30 count bottles with NDC #23359-105-30 and samples with NDC #23359-105-05 and NDC #23359-105-01.

PHYSICIAN SAMPLE NOT FOR RESALE

Recommended Storage: 15°-30°C (59°-86°F) degrees. Protect from light moisture and avoid excessive heat. Dispense original carton.

KEEP OUT OF REACH OF CHILDREN

RX ONLY

CENTURION LABS, LLC
BIRMINGHAM, AL 35243

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 23359-105-30

C-Nate
DHA

Softgels

Omega-3 Fatty Acids (DHA-EPA)	200mg
Vitamin B ₁ (Thiamine Mononitrate)	3 mg
Vitamin B ₂ (Riboflavin)	3 mg
Vitamin B ₆ (Pyridoxine HCL)	20 mg
Vitamin B ₁₂ (Cyanocobalamin)	15 mcg
Folic Acid	1 mg

Vitamin D ₃ (Cholecalciferol)	400 IU
Vitamin C (Ascorbic Acid)	100 mg
Vitamin E (d-alpha tocopherol)	30 IU
Copper (Cupric Sulfate)	1 mg
Zinc (Zinc Oxide)	20 mg
Iron (Fumerate)	28 mg
Magnesium	30 mg

Rx Only

Net Contents: 30 softgels

Manufactured For:
Centurion Labs LLC

Distributed by:
Centurion Labs LLC
Birmingham, AL 35243

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

Dosage and Administration: Usual Adult dose: one softgel daily or as prescribed by your doctor.

WARNING: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient.

In case of accidental overdose call a doctor or poison control center immediately. Iron is toxic. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. C-Nate DHA should be stored beyond the reach of children to protect against accidental iron poisoning. Keep this and all drugs out of reach of children.

NDC 23359-105-30



Omega-3 Fatty Acids (DHA-EPA)	200 mg
Vitamin B1 (Thiamine Mononitrate)	3 mg
Vitamin B2 (Riboflavin)	3 mg
Vitamin B6 (Pyridoxine HCL)	20 mg
Vitamin B12 (Cyanocobalamin)	15 mcg
Folic Acid	1 mg
Vitamin D3 (Cholecalciferol)	400 IU
Vitamin C (Ascorbic Acid)	100 mg
Vitamin E (d-alpha tocopherol)	30 IU
Copper (Cupric Sulfate)	1 mg
Zinc (Zinc Oxide)	20 mg
Iron (Fumarate)	28 mg
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Rx Only

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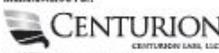
Precautions: General: Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematologic remission can occur with neurological manifestations remain progressive.

See package insert for full prescribing information.

Store at controlled room temperature, 15-30°C (59-86°F).

Dispense in a tight, light-resistant container with a child-resistant closure as defined in USP/NF.

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

Manufactured For:

CENTURION LABS, LLC

Distributed by:
Centurion Labs
Birmingham, AL 35243
Rev. 12/12



Lot:

Exp:

N 3 23359 10530 2

C-NATE DHA

omega-3 fatty acids, icosapent, doconexent, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, folic acid, cholecalciferol, ascorbic acid, .alpha.-tocopherol, d-, cupric sulfate, zinc oxide, ferrous fumarate and magnesium oxide capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:23359-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S)	OMEGA-3 FATTY ACIDS	200 mg

THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	20 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	30 [iU]
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	28 mg
MAGNESIUM (UNII: I38ZP9992A) (MAGNESIUM - UNII:I38ZP9992A)	MAGNESIUM	30 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	brown (annato)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	PRE;01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23359-105-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2013	
2	NDC:23359-105-05	5 in 1 CARTON; Type 0: Not a Combination Product	01/01/2013	
3	NDC:23359-105-01	1 in 1 PACKET; Type 0: Not a Combination Product	01/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2013	

Labeler - Centurion Labs, LLC (016481957)