

**COMPLETE NATAL DHA- .beta.-carotene, ascorbic acid, cholecalciferol,
.alpha.-tocopheryo acetate, dl, thiamine mononitrate, riboflavin, niacinamide,
pyridoxine hydrochloride, folic acid, cyanocobalamin, magnesium oxide, zinc
oxide, cupric oxide, and doconexent
Trigen Laboratories, LLC**

Complete Natal DHA

SUPPLEMENT FACTS

Multivitamin/Multimineral Tablet

Supplement Facts		
Serving Size: 1 Tablet		
Servings Per Container: 30		
	Amount Per Serving	% DV for Pregnant and Lactating Women
Vitamin A (as Beta-Carotene)	900 mcg RAE (3000 IU)	69%
Vitamin C (Ascorbic Acid)	120 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	67%
Vitamin E (as dl-Alpha Tocopheryl Acetate)	15 mg*	79%
Thiamin (as Thiamine Mononitrate)	1.8 mg	129%
Riboflavin	4 mg	250%
Niacin (as Niacinamide)	20 mg NE	111%
Vitamin B ₆ (as Pyridoxine HCl)	25 mg	1250%
Folate	1667 mcg DFE (1000 mcg Folic Acid)	278%
Vitamin B ₁₂ (as Cyanocobalamin)	12 mcg	429%
Calcium (as Calcium Carbonate)	200 mg	15%
Iron (from Ferrous Bisglycinate and Iron Protein Succinylate)	29 mg	107%
Magnesium (as Magnesium Oxide)	25 mg	6%
Zinc (as Zinc Oxide)	25 mg	192%
Copper (as Cupric Oxide)	2 mg	154%
*30 mg dl-Alpha Tocopheryl Acetate equivalent to 15 mg Alpha-Tocopherol		

Omega-3 Fatty Acid Capsule

Supplement Facts		
Serving Size: 1 Softgel Capsule		
Servings Per Container: 30		
	Amount Per Serving	% DV for Pregnant and Lactating Women
DHA (Docosahexaenoic Acid)	200 mg	†
† Daily Value (DV) not established		

Other Ingredients:

Tablets: Microcrystalline Cellulose, Croscarmellose Sodium, Tripotassium Citrate, Coating (Hypromellose, Polyethylene Glycol, Polysorbate 80, Castor Oil), Acacia, Citric Acid, Povidone K30, Fumed Silica, Magnesium Stearate and Stearic Acid

Soft gelatin capsules: Bovine Gelatin, Glycerin, Water, and Ethyl Vanillin.

THIS PRODUCT CONTAINS FISH OIL (ANCHOVIES & SARDINES).

Complete Natal DHA is a multivitamin/multimineral and omega-3 fatty acid supplement

indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the post-natal period for both lactating and non-lactating mothers.

CONTRAINDICATIONS

Supplemental vitamins and minerals should not be prescribed for patients with hemochromatosis or Wilson's disease. This product is contraindicated in patients with known hypersensitivity to any of the ingredients including fish oil.

WARNINGS

Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding.

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 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 remain progressive. Allergic sensitization has been reported following both oral and parenteral administration of folic acid. The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Safety and effectiveness in elderly populations have not been established.

DRUG INTERACTIONS

Complete Natal DHA is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin, Clopidogrel).

ADVERSE REACTIONS

Adverse reactions with iron therapy are usually transient and may include constipation,

diarrhea, nausea, vomiting, dark stool and abdominal pain.

DESCRIPTION

Complete Natal DHA tablets are clear coated, speckled light brown, oval tablets with debossed "01030" on one side. Complete Natal DHA soft gelatin capsules are oblong, clear transparent soft gel capsules containing a pale yellow oil/liquid.

DIRECTIONS FOR USE

Take one tablet and one soft gelatin capsule by mouth daily, or as prescribed by a physician. The tablet and soft gelatin capsule may be taken together or at different times of the day.

HOW SUPPLIED

Complete Natal DHA is supplied in a 30 day unit-of-use dispensing carton containing 6 blister cards of 5 tablets and 5 soft gelatin capsules each.

Product Code: 13811-010-30

STORAGE

Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Protect from moisture and excessive heat. Note that contact with moisture may produce surface discoloration of the tablet.

KEEP OUT OF REACH OF CHILDREN.

For use on the order of a healthcare practitioner.

Call your doctor about side effects. To report side effects, call Trigen Laboratories, LLC at 1-770-509-4500 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

PLR-COMNDHA-00001-1 Rev. 01/2022

Manufactured for:

Trigen Laboratories, LLC

Alpharetta, GA 30005

www.trigenlab.com



PRINCIPAL DISPLAY PANEL - Kit Carton

**TRIGEN
LABORATORIES**

13811-010-30

Complete Natal DHA

Prenatal Multivitamin/Multimineral Tablets and Omega-3 Fatty Acid Soft Gelatin Capsules

30 Tablets and 30 Soft Gelatin Capsules

(6 Unit-Dose Cards of 5 tablets and 5 soft gelatin capsules)

Complete Natal DHA

Prenatal Multivitamin/Multimineral Tablets and Omega-3 Fatty Acid Soft Gelatin Capsules



13811-010-30

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PLR-COMNDHA-00001-1

Rev. 1/2022

Manufactured for:
Trigen Laboratories, LLC
Alpharetta, GA 30005

www.trigenlab.com



Multivitamin/Multimineral Tablet

Supplement Facts

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Servings Per Container: 30

	Amount per Serving	% DV for Pregnant and Lactating Women
Vitamin A (as Beta-Carotene)	900 mcg RE (2000 IU)	69%
Vitamin C (ascorbic Acid)	120 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	67%
Vitamin E (as dl-Alpha Tocopheryl Acetate)	15 mg	76%
Thiamin (as Thiamine Mononitrate)	1.8 mg	129%
Riboflavin	4 mg	250%
Niacin (as Nicotinamide)	20 mg NE	111%
Vitamin B ₆ (as Pyridoxine HCl)	25 mg	1250%
Folate	1667 mcg DFE (1000 mcg Folic Acid)	278%
Vitamin B ₁₂ (as Cyanocobalamin)	12 mcg	429%
Calcium (as Calcium Carbonate)	200 mg	15%
Iron (as Iron Ferrous Bisphosphate and Iron Protein Succinylate)	29 mg	107%
Magnesium (as Magnesium Oxide)	25 mg	6%
Zinc (as Zinc Oxide)	25 mg	192%
Copper (as Copper Oxide)	2 mg	154%
*30 mg dl-Alpha Tocopheryl Acetate equivalent to 15 mg Alpha-Tocopherol		

Omega-3 Fatty Acid Capsule

Supplement Facts

Serving Size: 1 Softgel Capsule
Servings Per Container: 30

	Amount per Serving	% DV for Pregnant and Lactating Women
DHA (Docosahexaenoic Acid)	200 mg	†
† Daily Value (DV) not established		

Complete Natal DHA

Other Ingredients: Tablets: Microcrystalline Cellulose, Croscarmellose Sodium, Tripartite Cellulose, Croscarmellose Sodium, Polyethylene Glycol, Polysorbate 80, Gator Oil, Amara, Citric Acid, Povidone K30, Fumed Silica, Magnesium Stearate and Stearic Acid

Soft gelatin capsules: Bovine Gelatin, Glycerin, Water, and Ethyl Vanillin. **THIS PRODUCT CONTAINS FISH OIL (ANCHOVIES & SARDINES).** Complete Natal DHA is a multivitamin/multimineral and omega-3 fatty acid supplement indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the post-natal period for both lactating and non-lactating mothers.

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WARNINGS: Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding.

PRECAUTIONS: General: Folic acid is a major 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 remain progressive. Allergic sensitization has been reported following both oral and parenteral administration of fish oil.

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Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Safety and effectiveness in elderly populations have not been established.

DRUG INTERACTIONS: Complete Natal DHA is not recommended for use and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin, Clopidogrel).



COATING FREE AREA

COMPLETE NATAL DHA

.beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherylo acetate, dl, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, magnesium oxide, zinc

oxide, cupric oxide, and doconexent kit

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:13811-010
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-010-30	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	30
Part 2	1 BLISTER PACK	30

Part 1 of 2

COMPLETE NATAL DHA

.beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopheryo acetate, dl, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, magnesium oxide, zinc oxide, and cupric oxide tablet, film coated

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	3000 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	120 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]
.Alpha.-Tocopherol Acetate, DL- (UNII: WR1WPI7EW8) (.Alpha.-Tocopherol, DL- - UNII:7QWA1RIO01)	.Alpha.-Tocopherol, DL-	30 mg
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.8 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	4 mg
Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	20 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	25 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	12 ug
Calcium Carbonate (UNII: H0G9379FGK) (Calcium Cation - UNII:2M83C4R6ZB)	Calcium Carbonate	200 mg
Ferrous Bisglycinate (UNII: SFW1D987QV) (Ferrous Cation - UNII:GW89581OWR)	Ferrous Cation	29 mg
Magnesium Oxide (UNII: 3A3U0GI71G) (Magnesium Cation - UNII:T6V3LHY838)	Magnesium Oxide	25 mg

Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	25 mg
Cupric Oxide (UNII: V1XJQ704R4) (Cupric Cation - UNII:8CBV67279L)	Cupric Cation	2 mg

Inactive Ingredients

Ingredient Name	Strength
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
CASTOR OIL (UNII: D5340Y2I9G)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Hypromelloses (UNII: 3NXW29V3WO)	
Acacia (UNII: 5C5403N26O)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Povidone K30 (UNII: U725QWY32X)	
Magnesium Stearate (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Stearic acid (UNII: 4ELV7Z65AP)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		06/01/2010	

Part 2 of 2

COMPLETE NATAL DHA

doconexent capsule

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Doconexent (UNII: ZAD9OKH9JC) (Doconexent - UNII:ZAD9OKH9JC)	Doconexent	200 mg

Inactive Ingredients

Ingredient Name	Strength
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GELATIN TYPE B BOVINE (200 BLOOM) (UNII: A7JR5F8DLH)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
.Alpha.-Tocopherol (UNII: H4N855PNZ1)	
Ethyl Vanillin (UNII: YC9ST449YJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		06/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		06/01/2010	

Labeler - Trigen Laboratories, LLC (830479668)

Revised: 1/2022

Trigen Laboratories, LLC