

**DUET DHA 400- .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, iron, magnesium oxide, zinc oxide, cupric oxide, iodine, omega-3 fatty acids  
Eckson 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](#).*

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## **Duet DHA 400**

### **DESCRIPTION:**

This product is a gluten free prescription regimen of prenatal multi-vitamin, multi-mineral and omega-3 fatty acids, supplied as tablets and softgel capsules.

### **Each tablet contains:**

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#### **Supplement Facts**

#### **Serving Size: 1 Tablet**

	<b>Amount Per Serving</b>
Vitamin A (beta carotene)	2,800 IU
Vitamin C (ascorbic acid)	120 mg
Vitamin D (cholecalciferol)	820 IU
Vitamin E (dl-alpha tocopheryl acetate)	3 mg
Vitamin B <sub>1</sub> (thiamine mononitrate)	1.8 mg
Vitamin B <sub>2</sub> (riboflavin)	4 mg
Niacinamide	20 mg
Vitamin B <sub>6</sub> (pyridoxine hydrochloride)	50 mg
Folic acid	1 mg
Vitamin B <sub>12</sub> (cyanocobalamin)	12 mcg
Calcium (calcium carbonate)	200 mg
Iron (polysaccharide iron complex and sodium iron (III) ethylenediaminetetraacetate, Ferrazone <sup>®</sup> )	25 mg
Magnesium (magnesium oxide)	25 mg
Zinc (zinc oxide)	25 mg
Copper (cupric oxide)	2 mg
Iodine	220 mcg

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**OTHER INGREDIENTS:** microcrystalline cellulose, starch, silica, magnesium stearate, polyethylene glycol, polyvinyl alcohol, titanium dioxide, talc, FD&C red no. 40 aluminum lake, FD&C blue no. 1 & no. 2 aluminum lake

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**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.

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**Each softgel capsule contains** in a clear solution of 400 mg purified omega-3 long-chain fatty acids including DHA (docosahexaenoic acid) and EPA (eicosapentaenoic acid).

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#### **Supplement Facts**

**Serving Size: 1 Softgel Capsule**

#### **Amount Per Serving**

Total omega-3 long-chain fatty acids (as DHA and EPA)

400 mg

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**OTHER INGREDIENTS:** gelatin, glycerin, purified water

#### **INDICATIONS:**

This product is a gluten free prescription regimen of prenatal multi-vitamin, multi-mineral and omega-3 fatty acid supplements indicated for use in improving the nutritional status of women throughout pregnancy and in the post-natal period for both lactating and non-lactating mothers. This product is also useful in improving the nutritional status prior to conception.

#### **CONTRAINDICATIONS:**

This product is contraindicated in patients with known hypersensitivity to any of the ingredients, including fish or fish oil.

#### **WARNINGS:**

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B<sub>12</sub> is deficient.

Since daily ingestion of more than 3 grams per day of omega-3 fatty acids, including alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), from fish oils may have potential antithrombotic activities and may increase bleeding times, administration of DHA should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants.

**KEEP OUT OF REACH OF CHILDREN.**

#### **PRECAUTIONS:**

Folic acid in doses above 0.1 mg daily may obscure the diagnosis of pernicious anemia (hematologic remission may occur while neurological manifestations remain progressive).

#### **DRUG INTERACTIONS:**

Pyridoxine supplements should be avoided in patients receiving levodopa alone, as the actions of levodopa may be antagonized.

### **ADVERSE REACTIONS:**

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

### **DOSAGE AND ADMINISTRATION:**

Before, during and after pregnancy, one tablet and one softgel capsule taken by mouth daily or as directed by a physician. The tablet and softgel capsule may be taken together or at different times of the day. Caution should be exercised to ensure that the prescribed dose of DHA does not exceed 1 gram (1,000 mg) per day.

### **HOW SUPPLIED:**

A 30-day regimen supplied in a carton, NDC 44118-807-30, consisting of one bottle containing 30 maroon tablets, imprinted "800", and one bottle containing 30 softgel capsules. These child-resistant bottles are tamper evident by foil seal under cap.

### **STORAGE:**

Store at controlled room temperature 20° to 25°C (68° to 77°F), excursions permitted to 15° to 30°C (59° to 86°F). Relative humidity not to exceed 65%. Protect from moisture, excessive heat and freezing. Note that contact with moisture may produce surface discoloration of the tablet.

**To report** a serious adverse event or obtain product information, call 1-855-899-4237.

[www.DuetDHA.com](http://www.DuetDHA.com)

Manufactured for:  
Eckson Labs, LLC  
1000 N. West St., Suite 1200, #927  
Wilmington, DE 19801

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## DUET DHA 400

.beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, iron, magnesium oxide, zinc oxide, cupric oxide, iodine, omega-3 fatty acids kit

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:44118-807
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44118-807-30	1 in 1 CARTON; Type 0: Not a Combination Product	09/09/2011	04/30/2024

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	30
Part 2	1 BOTTLE	30

## Part 1 of 2

### DUET

.beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, iron, magnesium oxide, zinc oxide, cupric oxide, iodine tablet

#### Product Information

**Item Code (Source)** NDC:44118-803

**Route of Administration** ORAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>.BETA.-CAROTENE</b> (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	2800 [iU]
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	820 [iU]
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	3 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.8 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	4 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	50 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
<b>IRON</b> (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	25 mg
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
<b>CUPRIC OXIDE</b> (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg
<b>IODINE</b> (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	220 ug

#### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL</b> (UNII: 532B59J990)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	

Product Characteristics

Color	red (maroon)	Score	no score
Shape	CAPSULE (caplet)	Size	20mm
Flavor		Imprint Code	800
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44118-803-30	30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/09/2011	04/30/2024

Part 2 of 2

DUET DHA

omega-3 fatty acids capsule, gelatin coated

Product Information

Item Code (Source)	NDC:44118-805
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	400 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44118-805-30	30 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/09/2011	04/30/2024

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/09/2011	04/30/2024

**Labeler** - Eckson Labs, LLC (078435242)

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Eckson Labs, LLC