

**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**

	<b>Amount Per Serving</b>
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

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

Ferrazzone® is a registered trademark of AkzoNobel b v  
 1800009 v1 Rev. 07/2018

**DESCRIPTION:** This product is a gluten free prescription regimen of prenatal multivitamin, mineral, and omega-3 fatty acids, supplied as tablets and softgel capsules. Each tablet contains:

Supplement Facts	
Serving Size: 1 Tablet	
	Amount Per Serving
Vitamin A (beta carotene)	2,800 IU
Vitamin D (cholecalciferol)	120 mg
Vitamin E (d-alpha-tocopherol acetate)	820 IU
Vitamin B1 (thiamine mononitrate)	1.5 mg
Vitamin B2 (riboflavin)	4 mg
Niacinamide	20 mg
Vitamin B6 (pyridoxine hydrochloride)	30 mg
Folic acid	1 mg
Vitamin B12 (cyanocobalamin)	12 mcg
Calcium (calcium carbonate)	200 mg
Iron (polysaccharide iron complex and sodium iron citrate)	25 mg
Magnesium (magnesium oxide)	25 mg
Zinc (zinc oxide)	25 mg
Copper (cupric oxide)	2 mg
Iodine	225 mcg

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

**WARNINGS:** 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.

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

Supplement Facts	
Serving Size: 1 Softgel Capsule	
	Amount Per Serving
Total omega-3 long-chain fatty acids (as DHA and EPA)	400 mg

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

**INDICATIONS:** This product is a gluten free prescription regimen of prenatal multivitamin, mineral, and omega-3 fatty acid supplements indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating 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.

Rx Only

NDC 44118-807-30

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.

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

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18000010 v1 Rev. 07/2018

when one heart becomes two

**DuetDHA 400**

Prescription Prenatal Vitamins

Features an innovative blend of iron and omega-3 long-chain fatty acids

30 day supply = 30 tablets and 30 softgel capsules  
 By **Eckson Labs**

GLUTEN FREE  
 & 400mg Omega-3

**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	

## 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
.BETA.-CAROTENE (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	2800 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	820 [iU]
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	3 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:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	50 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 CATION	200 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	25 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg

IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	220 ug
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### Inactive Ingredients

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

## 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	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)				
ETHYL VANILLIN (UNII: YC9ST449YJ)				
<b>Product Characteristics</b>				
Color	yellow	Score	no score	
Shape	CAPSULE	Size	16mm	
Flavor		Imprint Code		
Contains				
<b>Packaging</b>				
#	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		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		09/09/2011		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		09/09/2011		

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

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Eckson Labs, LLC