

**DOTHELLE DHA- ferrous fumarate, iron, ascorbic acid, folic acid, thiamine mononitrate, riboflavin, niacin, calcium pantothenate, pyridoxine hydrochloride, biotin, cyanocobalamin, cupric sulfate, magnesium sulfate, unspecified form, zinc sulfate, unspecified form, omega-3 fatty acids, doconexent and icosapent capsule, liquid filled  
Method Pharmaceuticals, LLC**

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**Dothelle DHA**

**STATEMENT OF IDENTITY:**

Dothelle DHA is an orally administered prescription dietary supplement and should be administered under the supervision of a licensed medical practitioner.

**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.

**DOSAGE AND ADMINISTRATION:**

Adults (persons over 12 years of age), One (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

**Supplement Facts**

**Servings per Bottle: 30**

**Serving Size: 1 Capsule %DV for Pregnant**

**Each Capsule contains and Lactating Women**

**Ferrous Fumarate (anhydrous) 53.5 mg**

(Equiv. to about 17.5 mg of Elemental Iron)

**Polysaccharide Iron Complex 38 mg 194% ¶**

(Equiv. to about 17.5 mg of Elemental Iron)

**Vitamin C\* 25 mg 42%**

**Folic Acid 1 mg 125%**

**Vitamin B1 (thiamine mononitrate) 2 mg 118%**

**Vitamin B2 (riboflavin) 3 mg 150%**

**Vitamin B3\* 1.8 mg 9%**

**Vitamin B5 (d-calcium pantothenate) 5 mg 50%**

**Vitamin B6 (pyridoxine HCl) 25 mg 1000%**

**Vitamin B7 (biotin) 300 mcg 100%**

**Vitamin B12 (cyanocobalamin) 12.5 mcg 156%**

**Copper (as copper sulfate) 2 mg 100%**

**Magnesium (as magnesium sulfate) 5 mg 1%**

**Zinc** (as zinc sulfate) **10 mg 67%**

**Omega-3 Fatty acids**† **200 mg ‡**

**DHA** (docosahexaenoic acid) **156 mg ‡**

**EPA** (eicosapentaenoic acid) **39 mg ‡**

\* Also containing Ascorbic Acid Precursors as **(1)** Acid Metabolites including niacinamide ascorbate, calcium ascorbate, magnesium ascorbate, potassium ascorbate and sodium ascorbate **(2)** Basic Amino Acids including lysine acetate; **(3)** Flavonoids including hesperidin; and **(4)** Glutathione.

¶ Total Iron: Ferrous Fumarate + Polysaccharide Iron Complex.

† At least 200 mg Omega-3 Fatty Acids derived from 310 mg fish oil. ‡ Daily value not established.

ALSO CONTAINS: Gelatin, Glycerin, Soy Lecithin, Yellow Beeswax, Natural Creamy Orange Flavour, L-Lysine Acetate, Hesperidin Complex, D&C Blue # 1, Sodium Citrate, Titanium Dioxide, Ethyl Vanillin, L-Glutathione, FD&C Yellow # 6.

HOW SUPPLIED: The Dothelle DHA capsule is an oval, blue soft gelatin capsule, and is imprinted with "M121". Dothelle DHA is dispensed in child-resistant bottles of 30 capsules.

#### **PRECAUTIONS/WARNING:**

**WARNING:** Ingestion of more than 3 grams of omega-3 fatty acids from fish oils per day may have potential antithrombotic effects, including an increased bleeding time and INR (International Normalized Ratio). Omega-3 fatty acids from fish oils (e.g., DHA) should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants.

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

#### **PRECAUTIONS**

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

**Pediatric Use:** Safety and effectiveness of this product have not been established in pediatric patients.

**Geriatric Use:** No clinical studies have been performed in patients 65 and older to determine whether older persons respond differently from younger persons. Dosage should always begin at the low end of the dosage scale and should consider that elderly persons may have decreased hepatic, renal, or cardiac function and/or concomitant diseases.

**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 light and moisture. Dispense in a tight, light-resistant container.

#### **HEALTH CLAIMS:**

Prescription Vitamin B9 Containing Dietary Supplement

#### **PRINCIPAL DISPLAY PANEL**

**NDC 58657-121-30**

**Dothelle DHA**

**Softgels**

**Rx**

**30 Capsules**

**DESCRIPTION:** Dohelle DHA is a prescription prenatal vitamin-mineral preparation containing omega-3 fatty acid supplements. The Dohelle DHA capsule is an oval, blue soft gelatin capsule, and is imprinted with "M121".

**RECOMMENDED USE:** Adults (persons over 12 years of age), One (1) capsule daily, between meals, or as prescribed by physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

**STORAGE:** Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP controlled room temperature].

**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.

Call your doctor about side effects. You may report side effects by calling 877-250-3427.

KEEP OUT OF REACH OF CHILDREN.

Manufactured For: Method Pharmaceuticals, LLC  
Arlington, TX 76006

Rev. 08/15



58657-121-30

**Dohelle DHA**  
**Softgels**

with Ascorbic Acid Precursors  
**PRENATAL MULTIVITAMIN SUPPLEMENT**

**Rx**  
**30 Capsules**



**Supplement Facts**

Servings per Bottle: 30

Each Capsule contains		%DV for Pregnant and Lactating Women
Ferrous Fumarate (anhydrous)	53.5 mg	
(Equiv. to about 17.5 mg of Elemental Iron)		
Polysaccharide Iron Complex	38 mg	194%†
(Equiv. to about 17.5 mg of Elemental Iron)		
Vitamin C	25 mg	42%
Folic Acid	1 mg	125%
Vitamin B1 (thiamine mononitrate)	2 mg	118%
Vitamin B2 (riboflavin)	3 mg	150%
Vitamin B3	1.8 mg	9%
Vitamin B5 (d-calcium pantothenate)	5 mg	50%
Vitamin B6 (pyridoxine HCl)	25 mg	1000%
Vitamin B7 (biotin)	300 mcg	100%
Vitamin B12 (cyanocobalamin)	12.5 mcg	156%
Copper (as copper sulfate)	2 mg	100%
Magnesium (as magnesium sulfate)	5 mg	1%
Zinc (as zinc sulfate)	10 mg	67%
Omega-3 Fatty acids†	200 mg	‡
DHA (docosahexaenoic acid)	156 mg	‡
EPA (eicosapentaenoic acid)	39 mg	‡

\* Also containing Ascorbic Acid Precursors as (1) Acid Metabolites including niacinamide ascorbate, calcium ascorbate, magnesium ascorbate, potassium ascorbate and sodium ascorbate (2) Basic Amino Acids including lysine ascorbate; (3) Flavonoids including hesperidin; and (4) Glutathione.  
† Total Iron: Ferrous Fumarate + Polysaccharide Iron Complex.  
‡ At least 200 mg Omega-3 Fatty Acids derived from 310 mg fish oil. † Daily value not established.

**DOTHELLE DHA**

ferrous fumarate, iron, ascorbic acid, folic acid, thiamine mononitrate, riboflavin, niacin, calcium pantothenate, pyridoxine hydrochloride, biotin, cyanocobalamin, cupric sulfate, magnesium sulfate, unspecified form, zinc sulfate, unspecified form, omega-3 fatty acids, doconexent and icosapent capsule, liquid filled

**Product Information**

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:58657-121
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	53.5 mg
<b>IRON</b> (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	38 mg
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	25 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE	2 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
<b>NIACIN</b> (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	1.8 mg
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12.5 ug
<b>CUPRIC SULFATE</b> (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNSPECIFIED FORM	5 mg
<b>ZINC SULFATE, UNSPECIFIED FORM</b> (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 mg
<b>OMEGA-3 FATTY ACIDS</b> (UNII: 71M78END5S) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S)	OMEGA-3 FATTY ACIDS	200 mg
<b>DOCONEXENT</b> (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	156 mg
<b>ICOSAPENT</b> (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	39 mg

## Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LYSINE ACETATE (UNII: TTL6G7LIWZ)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:58657-121-30	30 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		08/20/2015	

## Supplement Facts

Serving Size : Serving per Container :

	Amount Per Serving	% Daily Value
color		
flavor		
imprint		
scoring	1	
shape		
size (solid drugs)	15 mm	

**Labeler** - Method Pharmaceuticals, LLC (060216698)