

PRE-TABS DHA PRENATAL MULTI-VITAMIN/MINERAL SUPPLEMENT WITH DHA/EPA- sodium ascorbate, cholecalciferol, di-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hcl, folic acid, cyanocobalamin, calcium formate, calcium carbonate, ferrous (ii) bis-glycinate chelate, potassium iodide, zinc oxide, choline bitartrate, with doconexent and icosapent
DEREMETRX 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.

Pre-Tabs DHA Prenatal Multi-vitamin/Mineral Tablet

Descripton: Pre-Tabs DHA combination tablet-capsule for oral administration is a light blue capsule-shaped film coated tablet with a pleasant sweet flavor with WC001 imprinted on one side of the tablet and a light amber soft gel capsule omega-3 fatty acid containing both DHA and EPA.

Indications and Usage: Pre-Tabs DHA is indicated to provide vitamin/mineral and omega-3 fatty acid supplementation to women throughout pregnancy, during the postnatal for both lactating and nonlactating mothers. Pre-Tabs DHA is also beneficial in improving the nutritional status of women prior to conception.

Contraindications: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients .

Warnings: Ingestion of more than 3 grams of omega-fatty acids per day has been shown to have potential antithrombotic effects, including increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis. Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient.

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

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

Precautions: Folic acid in doses above 0.1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. This product contains formate, which if consumed above the recommended level, could cause visual impairment and other health effects. Do not take more than the recommended amount. If you are pregnant, nursing, or taking any medications consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Not intended for use by persons under the age of 18.

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

Dosage and Administration: Pre-Tabs DHA - One tablet and one soft gel capsule daily or as directed by a physician.

How Supplied: Pre-Tabs DHA tablets for oral administration are supplied as six child-resistant blister cards containing 5 tablets and 5 softgel capsules each (NDC# 48648-406-30).

Pre-Tabs DHA

Prenatal Multi-vitamin/Mineral Supplement

Gluten Free

NDC 48948-406-30 (30 count)

6 blister cards

each containing 5 tablets and 5 capsules

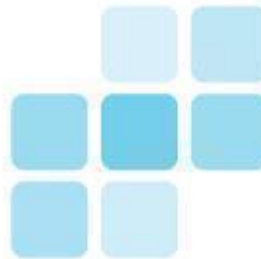
877-774-4949

www.dermetrx.com

Pre-Tabs™ DHA

Prenatal Multi-vitamin/Mineral Supplement

Gluten Free • DHA/EPA Capsule



NDC 48948-406-30 (30 count)

6 blister cards;

each containing 5 tablets and 5 capsules

Pre-Tabs™ DHA Prenatal Multi-vitamin/Mineral Tablets with DHA and Choline

Indications and Usage: Pre-Tabs™ DHA is indicated to provide vitamin/mineral and omega-3 fatty acid supplementation to women throughout pregnancy, during the postnatal for both lactating and nonlactating mothers. Pre-Tabs™ DHA is also beneficial in improving the nutritional status of women prior to conception.

Contraindications: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

Warnings: Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

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

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

Precautions: Folic acid in doses above 0.1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. This product contains formate, which if consumed above the recommended level, could cause visual impairment and other health effects. Do not take more than the recommended amount. If you are pregnant, nursing, or taking any medications consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Not intended for use by persons under the age of 18.

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

Dosage and Administration: Pre-Tabs™ DHA - One tablet and one soft gel capsule daily or as directed by a physician.

How Supplied: Pre-Tabs™ DHA tablets for oral administration are supplied as six child-resistant blister cards containing 5 tablets and 5 softgel capsules each (NDC # 48948-406-30).

Store at controlled room temperature 15°-30°(59°-86°F) RX only

PDH-A-0813

Distributed by:

DermetRx Pharmaceuticals
Gilbert, AZ 85233 • (877) 774-4949

Fomical® is a registered trademark of
Nephro-Tech 1, LLC

US Patent #6,528,542

Pre-Tabs™ is a trademark of
DermetRx L.L.C.

Supplement Facts

Serving Size: 1 Tablet

	Amount per Serving	% DV
Vitamin C (Sodium Ascorbate)	120 mg	200%
Vitamin D-3 (Cholecalciferol)	450 IU	112%
Vitamin E (d-alpha-Tocopheryl Acetate)	30 IU	100%
Vitamin B-1 (Thiamine Mononitrate)	3 mg	176%
Vitamin B-2 (Riboflavin)	3 mg	150%
Niacin (Nicotinamide)	20 mg	100%
Vitamin B-6 (Pyridoxine HCL)	50 mg	2000%
Folic Acid	1000 mcg	125%
Vitamin B-12 (Cyanocobalamin)	10 mcg	125%
Calcium	200 mg	15%
as Fomical® (Calcium Formate 150 mg) (Calcium Carbonate 45 mg)		
Iron (Ferrous (II) Bis-Glycinate Chelate)	32 mg	178%
Iodine (Potassium Iodide)	100 mcg	67%
Zinc (Zinc Oxide)	10 mg	67%
Choline (Choline Bitartrate)	55 mg	**

% Daily Value for Pregnant and Lactating Women: ** DV Not Established.

Other Ingredients: Microcrystalline Cellulose, Polyvinyl Alcohol, Polydioxane, Titanium Dioxide, PEG 3350, Talc, Maltodextrin, Magnesium Stearate, FD&C Blue #1, Polyacrylate 88, Carnauba Wax, Sodium Stearoyl

Each Omega-3 DHA gelatin capsule contains:
Docosahexaenoic Acid (DHA) 200 mg and
Eicosapentaenoic Acid (EPA) 30 mg derived from fish oils
(product of Norway)

Other ingredients in the DHA gelatin capsule:
Vitamin E (d-alpha-tocopherol) 2 IU, gelatin, glycerin, purified water

Pre-Tabs™ DHA

Prenatal Multi-vitamin/Mineral Supplement

Gluten Free • DHA/EPA Capsule



Gilbert, AZ 85233 • (877) 774-4949 • www.dermetrx.com



PRE-TABS DHA PRENATAL MULTI-VITAMIN/MINERAL SUPPLEMENT WITH DHA/EPA

sodium ascorbate, cholecalciferol, di-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hcl, folic acid, cyanocobalamin, calcium formate, calcium carbonate, ferrous (ii) bis-glycinate chelate, potassium iodide, zinc oxide, choline bitartrate, with doconexent and icosapent kit

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:48948-406

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48948-406-30	6 in 1 CARTON		
1		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	5 PACKAGE	5
Part 2	5 PACKAGE	5

Part 1 of 2

PRE-TABS DHA MULTI-VITAMIN/MINERAL SUPPLEMENT

sodium ascorbate, cholecalciferol, di-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hcl, folic acid, cyanocobalamin, calcium formate, calcium carbonate, polysaccharide iron complex, potassium iodide, zinc oxide, choline bitartrate tablet

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	SODIUM ASCORBATE	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	450 [iU]
TOCOPHERSOLAN (UNII: O03S90U1F2) (TOCOPHERSOLAN - UNII:O03S90U1F2)	TOCOPHERSOLAN	30 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	50 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
CALCIUM FORMATE (UNII: NP3JD65NPY) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	155 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	45 mg
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	32 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	100 ug
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 mg
CHOLINE BITARTRATE (UNII: 6K2W7T9V6Y) (CHOLINE - UNII:N91BDP6H0X)	CHOLINE	55 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
TALC (UNII: 7SEV7J4R1U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	blue (LIGHT BLUE)	Score	2 pieces
Shape	OVAL	Size	18mm
Flavor		Imprint Code	WC;001
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/15/2014	

Part 2 of 2

NESTABS ABC OMEGA 3-DHA

doconexent and icosapent supplement capsule, gelatin coated

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	230 mg
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	30 mg
ALPHA-TOCOPHEROL, D- (UNII: N9PR3490H9) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	ALPHA-TOCOPHEROL, D-	2 [iU]

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	yellow	Score	no score
Shape	capsule	Size	6mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/15/2014	

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Labeler - DEREMETRX LLC (079203275)**Registrant** - DEREMETRX LLC (079203275)