WESNATAL DHA COMPLETE- wesnatal dha complete Westminster Pharmaceuticals, LLC

WesNatal DHA Complete

Multivitamin/Multimineral Tablet

Supplement Facts Serving Size: Tablets

Serving 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 (Abscorbic 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 B6 (as Pyridoxine HCl)	25 mg	1250%
Folate	1667 mcg DFE (1000 mcg Folic Acid)	278%
Vitamin B12 (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) * 30 mg dl-Alpha Tocopheryl Acetate	2 mg	154%

^{* 30} mg dl-Alpha Tocopheryl Acetate equivalent to 15 mg Alpha-Tocopherol

Supplement Facts Serving Size: Softgel Capsule Serving 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 (Sodium Carboxymethylcellulose, Dextrin, Dextrose, Lecithin, Sodium Citrate), 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 SOY AND FISH OIL (ANCHOVIES & SARDINES).

WesNatal DHA Complete 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 ometa-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 alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} 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

WesNatal DHA Complete 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).

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.

ADVERSE REACTIONS

Adverse reactions with iron therapy are usually transient and may include constipation, diarrhea, nausea, vomiting, dark stool and abdominal pain.

DESCRIPTION

WesNatal Complete tablets are clear coated, speckled light brown, oval tablets with debossed "251" on one side. WesNatal DHA Complete 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

WesNatal DHA Complete 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: 69367-251-30

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 Westminster Pharmaceuticals, LLC at 1-844-221-7294 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured for: **Westminster Pharmaceuticals, LLC**Nashville, TN 37217
Made in Canada
500392
Rev. 02/23

PRINCIPAL DISPLAY PANEL - Kit Carton

69367-251-30 Rx

WesNatal DHA Complete

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)

Westminster Pharmaceuticals 69367-251-30 Rx

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Manufactured for:

Made in Canada

Westminster Pharmaceuticals, LLC Nashville, TN 37217 500392 Rev. 02/23





Multivitamin/Multimineral Tablet

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Copper (as Cupric Oxide)	2 mg	154%

Supplement Facts

Serving Size: Softgel Capsule Serving Per Container: 30

Omega-3 Fatty Acid Capsule

	Amount Per Serving	% DV for Pregnant and Lactating Women
DHA (Docosahexaenoic Acid)	200 mg	†

Other Ingredients: Tablets: Microcrystalline Cellulose, Croscarmellose Sodium, Tripotassium Citrate, Coating (Sodium Carboxymethylcellulose, Dextrin, Dextrose, Lecithin, Sodium Citrate), Acacia, Citric Acid, Povidone K30, Fumed Silica, Magnesium Stearate and Stearic Acid.

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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 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.

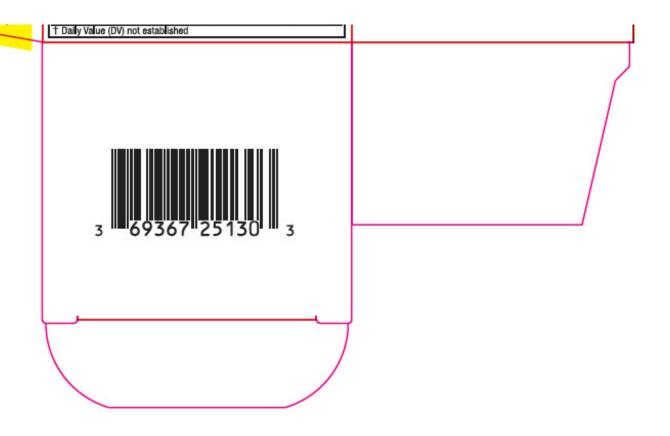
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WESNATAL DHA COMPLETE

wesnatal dha complete kit

Product Information

Product Type DIETARY SUPPLEMENT Item Code (Source) NHRIC:69367-251

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69367-251-30	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 BLISTER PACK	30
Part 2	6 BLISTER PACK	30

Part 1 of 2

WESNATAL DHA COMPLETE

wesnatal dha complete tablet

Product Information

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]	
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHATOCOPHEROL, DL UNII:7QWA1RIO01)	.ALPHATOCOPHEROL, DL-	30 mg	
THIAMINE MONONITRATE (UNII: 8K0104919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.8 mg	
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	4 mg	
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	20 mg	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	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	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
POTASSIUM CITRATE TRIHYDRATE (UNII: ZTT95BJ9Y0)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)		
ICODEXTRIN (UNII: 2NX48Z0A9G)		
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
ACACIA (UNII: 5C5403N26O)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
POVIDONE K30 (UNII: U725QWY32X)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
STEARIC ACID (UNII: 4ELV7Z65AP)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 BLISTER PACK		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
DIETARY SUPPLEMENT		03/31/2023	

Part 2 of 2

WESNATAL DHA COMPLETE

wesnatal dha complete capsule, gelatin coated

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

ETHYL VANILLIN (UNII: YC9ST449YJ)

ı			
	Ingredient Name	Basis of Strength	Strength
I	DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	200 mg

Inactive Ingredients Ingredient Name Strength GELATIN TYPE B BOVINE (200 BLOOM) (UNII: A7JR5F8DLH) GLYCERIN (UNII: PDC6A3C0OX) WATER (UNII: 059QF0KOOR)

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 BLISTER PACK		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
DIETARY SUPPLEMENT		03/31/2023				

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
DIETARY SUPPLEMENT		03/31/2023			

Establishment								
Name	Address	ID/FEI	Business Operations					
Nutra-Med Packaging, Inc.		022004902	PACK					

Revised: 4/2023

Westminster Pharmaceuticals, LLC