WESTGEL DHA- ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine hydrochloride, riboflavin, niacin, pyridoxine hydrochloride, levomefolate magnesium, folic acid, cyanocobalamin, iron pentacarbonyl, potassium iodide, magnesium oxide, doconexent, and icosapent capsule, liquid filled

Westminster Pharmaceuticals, LLC

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#### WestGel DHA

Supplement Facts		
Serving Size: 1 Softgel	Servings Per Container: 30	
Amount Per Serving	% Daily Value	% Daily Value for Pregnant & Lactating Women
Vitamin C (as ascorbic acid) 55 mg	61%	46%
Vitamin D3 (as cholecalciferol) 25 mcg (1000 IU)	125%	167%
Vitamin E (as d-alpha-tocopheryl acetate) 10 mg (15 IU)	67%	53%
Thiamin (as thiamine HCl, Vitamin B1) 1.3 mg	108%	93%
Riboflavin (Vitamin B2) 1.8 mg	138%	113%
Niacin (as nicotinic acid) 5 mg	31%	28%
Vitamin B6 (as pyridoxine HCl) 35 mg	2059%	1750%
Folate 1.7 mg DFE (400 mcg folic acid) (1 mg folate as 630 mcg of L- Methylfolate Magnesium, molar equivalent to 600 mcg of L-Methylfolic acid; and 400 mcg of folic acid)	425%	283%
Vitamin B12 (as cyanocobalamin) 14 mcg	583%	500%
Iron (as carbonyl iron) 31 mg	172%	115%
Iodine (as potassium iodide) 200 mcg	133%	69%
Magnesium (as magnesium oxide) 30 mg	7%	8%
Docosahexaenoic Acid (DHA) 200 mg	*	*
Eicosapentaenoate Acid (EPA) 15 mg	*	*

\* Daily Value not established

**Other Ingredients:** Gelatin (bovine), Glycerin, Purified Water, Yellow Beeswax, Soy Lecithin, Natural Creamy Orange Flavor, Caramel Powder, Ethyl Vanillin.

#### **Contains Soy and Fish**

WestGel DHA Softgel capsules are dye free, lactose, gluten and sugar free. They do not contain any artificial flavors or sweeteners. WestGel DHA contains bovine gelatin.

#### INDICATIONS

WestGel DHA is an orally administered multivitamin/multimineral fatty acid dietary supplement indicated to improve the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. WestGel DHA can also be beneficial in improving the nutritional status of women prior to conception<sup>1</sup>.

1 This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease.

#### CONTRAINDICATIONS

WestGel DHA is contraindicated in patients with a known hypersensitivity to any of the ingredients.

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.

Caution is recommended in patients taking anticonvulsant medications as folate may interfere with anticonvulsant medication, and may lower seizure threshold. Furthermore, anticonvulsant medications may interfere with folate metabolism.

#### PRECAUTIONS

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient. Folic acid is doses above 0.1 mg daily may obscure pernicious anemia that hematologic remission can occur while neurological manifestations progress.

Ingestion of more than 3 grams of omega-3 fatty acids (such as DHA and EPA) per day has been shown to have potential antithrombotic effects, including an increased bleeding time and International Normalized Ratio (INR). 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.

#### **ADVERSE REACTIONS**

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You should call your doctor for medical advice about serious adverse events. To report adverse side effects or to obtain product information, contact Westminster Pharmaceuticals, LLC at 1-844-221-7294.

## DIRECTIONS

## Adults

Take one softgel daily with or without food, or as prescribed by a healthcare practitioner.

#### Children under 12

Consult a doctor. Do not exceed the recommended dose.

### HOW SUPPLIED

WestGel DHA is available as oval, brown softgel capsules with a white imprint "WP234". A carton unit dose pack of 30 (3 child-resistant blister cards of 10 softgels each).

Store at 20°C-25°C (68°F-77°F); excursions permitted to 15°C-30°C (59°F-86°F) [See USP Controlled Room Temperature.]

WestGel DHA should be administered only under the direct supervision of a healthcare practitioner.

Avoid excessive heat, light and moisture.

#### Keep out of reach of children.

Tamper evident: Do not use if seal is broken or missing.

Rx

## PRINCIPAL DISPLAY PANEL - 30 Softgel Blister Pack Carton

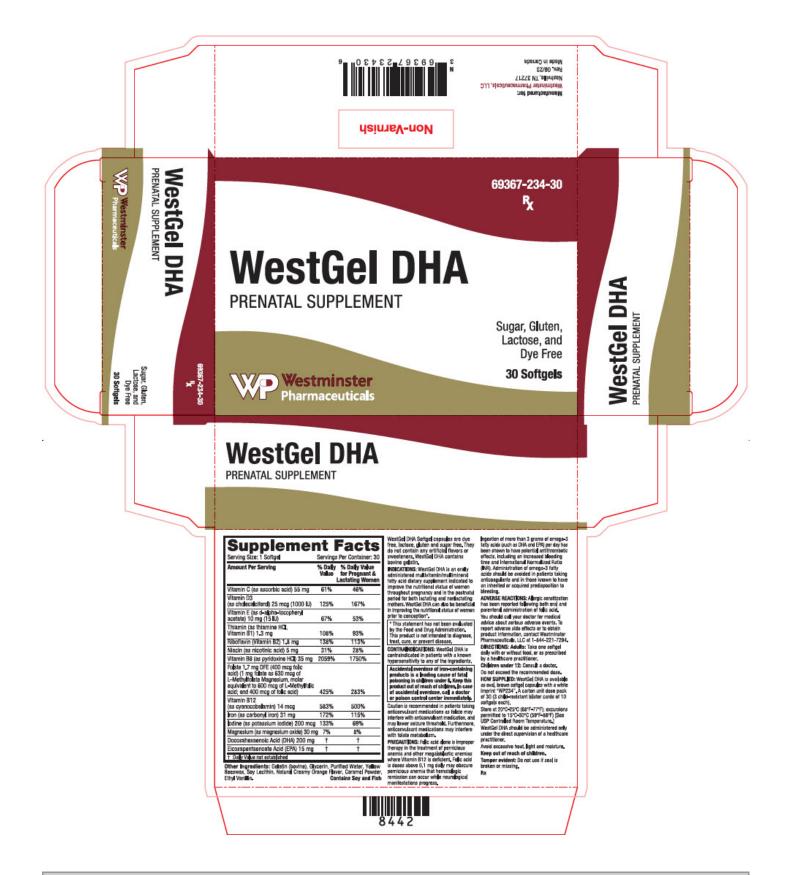
69367-234-30 Rx

WestGel DHA PRENATAL SUPPLEMENT

Sugar, Gluten, Lactose, and Dye Free

30 Softgels

Westminster Pharmaceuticals



# WESTGEL DHA

ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine hydrochloride, riboflavin, niacin, pyridoxine hydrochloride, levomefolate magnesium, folic acid, cyanocobalamin, iron pentacarbonyl, potassium iodide, magnesium oxide, doconexent, and icosapent capsule, liquid filled

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69367-234
Route of Administration	ORAL		
Route of Autimistration			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII: PQ6CK8PD0R)	ASCORBIC ACID	55 mg		
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	1000 [iU]		
<b>.ALPHATOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N) (.ALPHATOCOPHEROL, D UNII:N9PR3490H9)	.ALPHA TOCOPHEROL, D-	15 [iU]		
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	1.3 mg		
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	1.8 mg		
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	5 mg		
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	35 mg		
<b>LEVOMEFOLATE MAGNESIUM</b> (UNII: 1VZZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	600 ug		
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	400 ug		
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	14 ug		
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	31 mg		
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	200 ug		
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	30 mg		
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	200 mg		
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	15 mg		

# Inactive Ingredients

Ingredient Name	Strength
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CARAMEL (UNII: T9D99G2B1R)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ORANGE (UNII: 5EVU04N5QU)	

Ρ	Packaging			
#	Item Code	<b>Package Description</b>	Marketing Start Date	Marketing End Date
1	NHRIC:69367-234-30	3 in 1 CARTON		
1		10 in 1 BLISTER PACK		

# **Marketing Information**

Marketing

Application Number or Monograph Marketing Start Marketing End

Category	Citation	Date	Date
DIETARY SUPPLEMENT		01/23/2020	

Supplement Facts			
Serving Size :		Serving per Container :	
	<b>Amount Per Serving</b>	% Daily Value	
color			
scoring	1		
shape			
size (solid drugs)	10 mm		
imprint			
flavor			

# Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 7/2023

Westminster Pharmaceuticals, LLC