

FOLAWISE- beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, folic acid, levomefolate calcium, and cyanocobalamin tablet
Redmont Pharmaceuticals, LLC

FolaWise

71741-406-30

Multivitamin Dietary Supplement

Dispensed by Prescription

DESCRIPTION

FolaWise is a prescription multivitamin dietary supplement.

Supplement Facts		
Serving size: 1 Tablet		
Amount per Serving:	%Daily Value	
Vitamin A (as Beta-Carotene)	300 mcg RAE	33%
Vitamin C (as Ascorbic Acid)	90 mg	100%
Vitamin D3 (as Cholecalciferol)	20 mcg	100%
Vitamin E (as dl-Alpha Tocopherol Acetate)	4.5 mg (10 IU)	30%
Thiamin	1.2 mg	100%
Riboflavin	1.3 mg	100%
Vitamin B6 (as Pyridoxine HCl)	26 mg	1529%
Folate	1.67 mg DFE	418%
(from Folic Acid)	0.67 mg DFE	
(as 5-Methyl Tetrahydrofolate Calcium Salt)	1 mg DFE	
Vitamin B12 (as Cyanocobalamin)	13 mcg	542%

OTHER INGREDIENTS: Modified Cellulose, Croscarmellose Sodium, Stearic Acid, Silicon Dioxide, Magnesium Stearate, Titanium Dioxide, Polyethylene Glycol.

Preservative Free and Gluten Free. No sugar, starch, artificial colors, artificial flavors, wheat, yeast or corn added.

INDICATIONS

FolaWise is a prescription multivitamin that provides significant amounts of Vitamins B6, B12, C, D3, E, riboflavin, thiamine mononitrate, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop.

CONTRAINDICATIONS

FolaWise is contraindicated in patients with a known hypersensitivity to any the contained ingredients. Do not take this product if you are presently taking mineral oil, unless directed by a licensed medical practitioner.

PRECAUTIONS

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 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. FolaWise should only be used under the direction and supervision of a licensed medical practitioner.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You may report side effects by calling Redmont Pharmaceuticals, LLC at 1-800-986-5909.

DOSAGE AND ADMINISTRATION

One tablet daily directed by a physician.

HOW SUPPLIED

Bottles of 30 tablets (71741-406-30¹). Tablet is white, round.

1. Federal Register Notice of August 2, 1973 (38 FR20750)
2. Federal Register Notice of October 17, 1980 (45 FR69043, 69044)
3. Federal Register Notice of March 5, 1996 (61FR 8760)

1 Redmont Pharmaceuticals does not represent this product code to be National Drug Code (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies. This product is a prescription folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (64 FR 8760). 1-3 The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription. This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indications or claims of this product are not to be construed to be drug claims.

STORAGE AND HANDLING

STORAGE

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

[See USP Controlled Room Temperature.] Avoid excessive heat, light and moisture.

TAMPER EVIDENT: Do not use if seal is broken or missing.

MADE IN THE USA

Distributed by:
Redmont Pharmaceuticals, LLC
Birmingham, AL 35209
800-986-5909

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

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PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

71741-406-30

FolaWise

DIETARY SUPPLEMENT

30 TABLETS

Dispensed by Prescription

71741-406-30

FolaWise

DIETARY SUPPLEMENT

30 TABLETS

DISPENSED BY PRESCRIPTION

DOSAGE AND ADMINISTRATION:
Usual adult dosage is 1 tablet taken orally once daily or as prescribed by a licensed medical practitioner.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

STORAGE: Store at 20°-25°C (68°-77°F) excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Avoid excessive heat, light and moisture.

See package insert for full prescribing information.

REDMONT
PHARMACEUTICALS

Distributed by:
Redmont Pharmaceuticals, LLC
Birmingham, AL 35209
(800) 986-5909

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FOLAWISE

beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, folic acid, levomefolate calcium, and cyanocobalamin tablet

Product Information				
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:71741-406	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Beta Carotene (UNII: 01YAE03M7J) (Beta Carotene - UNII:01YAE03M7J)		Beta Carotene	300 ug	
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)		Ascorbic Acid	90 mg	
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)		Cholecalciferol	20 ug	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)		.ALPHA.-TOCOPHEROL ACETATE	4.5 mg	
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)		THIAMINE	1.2 mg	
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)		Riboflavin	1.3 mg	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)		PYRIDOXINE HYDROCHLORIDE	26 mg	
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)		Folic Acid	0.4 mg	
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)		LEVOMEFOLATE CALCIUM	0.6 mg	
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)		Cyanocobalamin	0.013 mg	
Inactive Ingredients				
Ingredient Name			Strength	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
Croscarmellose Sodium (UNII: M28OL1HH48)				
Stearic Acid (UNII: 4ELV7Z65AP)				
Silicon Dioxide (UNII: ETJ7Z6XBU4)				
MAGNESIUM PALMITOSTEARATE (UNII: R4OXA9G5BV)				
Titanium Dioxide (UNII: 15FIX9V2JP)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71741-406-30	30 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT			06/18/2025	

Supplement Facts

Serving Size :

Serving per Container :

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	11 mm	

Labeler - Redmont Pharmaceuticals, LLC (080843607)